FEASABILITY OF FOCUSED PARATHYROIDECTOMY IN DEVELOPING COUNTRIES - A Scoping Review

By

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As the candidate's supervisor I have approved this thesis for submission.

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Overview of The Thesis

Hyperparathyroidism (HPT) is characterized by pathologically excessive parathyroid hormone production. This may be as a consequence of pathology within the parathyroid gland (primary HPT) or as a sequela of pathology outside the parathyroid gland (secondary & tertiary HPT). The gold standard surgical management of HPT was bilateral neck exploration (BNE) but with improvement in localising methods, focused parathyroidectomy (FP) has made the gold standard contentious.

BNE, entailing a large neck incision and 4 gland exploration, demonstrates excellent cure rates of 95%. FP, whereby a single targeted miniature incision is made over the offending gland, is possible in the category of primary HPT as in up to 80% of cases the aetiology is a single gland adenoma. The prerequisites to embarking on this minimally invasive operative technique are accurate pre-operative localisation of the exact site of the offending gland adenoma and assistance of intra-operative adjuncts to confirm successful excision.

Considering the prerequisites required for FP, the initial concern of cost arose. Additionally, concerns of potential inferior success rates were initially entertained. Subsequently, numerous studies revealed this technique to be superior in terms of operative time; cost; convalescence; cosmesis; success rates and the ability to be performed under local anaesthetic, as a day case. As such, the current standard of care for primary HPT where a single gland adenoma is localised, is the FP.

The majority of the studies and trials demonstrating the superiority of FP emanate from developed high-income countries where there is a relative abundance of resources, and as such, the questioning of applicability or relevance of these studies to developing middle-income countries is valid. With the natural hesitancy to adopt these recommendations uncritically in developing countries, where the lack of resources might impede this technique, this concern of applicability, and therefore feasibility, needed to be addressed.

To address this, a scoping review of the literature was conducted, looking specifically at FP, pre-operative localisation and intra-operative adjuncts, in developing countries (upper and lower-middle income). The aim of this review was to ascertain if FP is feasible in these countries by assessing the availability and accuracy of pre-operative localisation, success of FP judged by cure rates and the availability and utility of intra-operative adjuncts.

This review will benefit surgeons in developing countries by demonstrating that FP is not an esoteric procedure described in ivory towers to be entertained in reverie only. Dispelling the myth of non-applicability due to resource constraints, by establishing the technique to be feasible in developing countries, more local surgeons can now, for localised single parathyroid gland adenomas, diverge away from knee-jerk routine bilateral neck explorations. Reassured with support of relevant local literature, they may now confidently embark on learning and performing the technique of FP resulting in satisfied patients who enjoy the superior outcomes associated with this technique.

Ethics Declaration

This study has been approved by the University of Kwa-Zulu Natal Biomedical Research Ethics Committee (BREC).

BREC reference: BREC/00005172/2023

Dedication

I would like to dedicate this dissertation to my parents, Dr Robin Rugnath and Mrs Ravina Rugnath. Words truly cannot express enough the immense gratitude I have for all that you have done for me.

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I would like to acknowledge my partner, Dr Kaileigh Veeran, for the unwavering support and love given to me throughout this journey. I would not be who I am today and would not have achieved even a fraction of what I have without you.

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Part 1: The Review of Literature

Anatomy of Parathyroid Glands

The parathyroid glands (PG), originally described in 1852 by Richard Owen, and subsequently described in humans for the first time in 1880 by Ivar Sandstrom, are endocrine glands located in the neck, posterior to the thyroid gland (1,2). Usually, there are 4 glands - 2 superior and 2 inferior, however they can vary in location (intrathyroidal or ectopic) and number (reduced in number or supernumerary) due to embryological variations. Intra-thyroidal PG's are relatively rare, with a reported rate of 2%, while ectopic glands, which may be located anywhere along a line from the angle of the mandible superiorly, down to the mediastinum inferiorly, vary in prevalence, with rates ranging between 2% - 43% (3,4). Variability in number, both reduction and additional supernumerary glands, are seen in about 19% of cases (5).

Physiology of Parathyroid glands

The PG are responsible for maintaining calcium equilibrium within the body. This is achieved through the formation and release of parathyroid hormone (PTH), which maintains eucalcaemia by responding to a series of negative feedback loops. When serum calcium levels are low, via a negative feedback loop, PTH is released from the PG which triggers: resorption of calcium from bone; resorption of calcium, in exchange for phosphate, at the kidneys and release of α-1-hydroxylase from the kidneys, which activates vitamin D causing an increase in calcium absorption from the gastrointestinal tract. Additionally, PTH release is stimulated by elevated persists unabated and is futile as the kidneys have reduced functional capacity in CKD, and as such, are unable to appropriately respond to PTH. As a result, all 4 PG are culprits in the cause of HPT in this scenario, as they each respond continuously to the inappropriate levels of calcium and phosphate. Treatment may involve pharmacotherapeutics such as calcimimetics, or operative management by parathyroidectomy (7).

Tertiary HPT represents a disease progression from secondary HPT, whereby the PG undergo hyperplasia from incessant stimulation, resulting in autonomous function. Even after the CKD may be completely addressed with a renal transplant, HPT in this scenario continues unrelenting, as a consequence of the now autonomous PG's. Similarly, the culprits here are all 4 PG, that have each undergone hyperplasia. Treatment involves parathyroidectomy (7).

Operative Options for Management For Parathyroid Gland Pathology

The operative management of HPT depends on the type of HPT, with secondary and tertiary HPT always requiring a 4-gland exploration and excision as the standard of care, known as a bilateral neck exploration (BNE). The operative management of primary HPT is contentious, as the aetiology in around 80% of cases is due only to a single gland adenoma, allowing for a more focused approach and thus obviating the need for 4 gland BNE. However, in cases of primary HPT where multi-gland adenomas are identified, a 4-gland BNE may be needed (7).

The History of Parathyroidectomy Approaches

The discovery of the PG in humans by *Ivor Sandstrom (1880)* was followed by nearly 3 decades of uncertainty regarding their function, with reports of inexplicable tetany following thyroidectomy, which was averted when these glands were preserved (2,9). *Professor*

Halsted, who is generally regarded as the most innovative and influential surgeon from the United States of America, with an astounding number of contributions to surgery, in 1907 reinforced the importance of the PG and their preservation when he stated, "*the fact that these little organs perform some highly important function is sufficient reason for the endeavor to preserve all of them"* (10,11). In 1909, *MacCallum et al* described hypocalcaemia as the cause of tetany in these patients after the PG were excised, and discovered the utility of calcium injections in reversing the condition (12). In the subsequent years, a clearer comprehensible understanding of the PG physiology and pathophysiology followed, culminating in the first successful parathyroidectomy by *Felix Mandl* in 1925 (13).

As a result of the prolific work across multiple years by *Cope et al* and *Churchill et al,* HPT was divided into 3 distinct classifications with the discovery of adenomatous or carcinomatous aetiology in cases of primary disease and diffuse hyperplasia in cases of secondary and tertiary disease (14-21). Additionally, the former was seen mostly in a single gland and rarely in 2 glands, with the latter, diffuse hyperplasia, seen in all 4 glands. These findings lead to Cope's suggestion of at least 2 gland exploration for cases of primary HPT and 4 gland exploration for secondary and tertiary HPT (14). This formed the basis for the myriad of evolutionary changes parathyroidectomy for primary HPT has undergone since the first parathyroidectomy 98 years ago.

Parathyroidectomy by cervical exploration and 4 gland exploration (BNE) was the unchallenged standard of care for the half century that followed Mandl's first successful procedure, with numerous publications released in that period supporting its effectiveness for all aetiology of HPT.
levels of phosphate, via a negative feedback loop, causing renal excretion of phosphate with retention of calcium in exchange, resulting from PTH's stimulatory effect on the kidneys (6).

Pathology of Parathyroid Glands

Hyperparathyroidism (HPT) is a pathological state in which excessive amounts of PTH is produced, with varying aetiologies, resulting in excessive levels of calcium termed hypercalcaemia. It may be broadly classified into primary, secondary and tertiary, with the majority of patients overall mostly asymptomatic (70% - 80% of cases) (7). The remaining cases of symptomatic presentation usually involve complaints grouped as 'stones, bones, groans and psychic moans', derived from renal stones, osteoclastic bone pain and/or fractures, abdominal moans from constipation or peptic ulceration pain and psychic groans from hypercalcaemic induced psychoses/depression (8).

Primary HPT is the most common form of this pathological state, and is the 3rd most common endocrine disorder globally (7). The aetiology is most often (80% of cases) a single gland adenoma, whilst the remaining causes include: multi-gland adenoma, parathyroid hyperplasia and parathyroid carcinoma. Primary HPT is managed operatively when the patient is symptomatic or asymptomatic and meets the international workshop of HPT criteria.

Secondary HPT most often occurs in patients with chronic kidney disease (CKD), where there is inadequate resorption of calcium and inadequate excretion of phosphate by the poorly functioning kidneys. This results in reduced calcium levels (hypocalcaemia) and elevated phosphate level (hyperphosphataemia), which stimulates the PG to produce PTH, in an effort to both raise the calcium levels and reduce the phosphate levels to normal. This process

Norris et al (1947) described their experience with 322 cases of parathyroid adenoma with successful operative management by a standard cervical exploration and 4 gland assessment (BNE) (22).

Black et al described their experience with surgical management of HPT in 63 patients in 1948, in 112 patients in 1953 and in 207 patients in 1956 (23-25). The authors recommended parathyroidectomy by way of cervical exploration with 4 gland assessment (BNE) as a standard approach in keeping with descriptions from colleagues. In the event that a 4th gland is not identified, the authors advised a complete cervical exploration including all known possible ectopic locations and thyroid incisions to identify intra-thyroidal PG. A full mediastinal exploration was only advised for follow up re-operative procedures.

Rienhoff et al (1950) reported experience with 27 cases of hyperparathyroidism with a specific focus on the surgical management (26). His approach mirrors the previous authors with a recommendation of a primary systematic approach by cervical exploration and 4 gland assessment (BNE), with continued search of the superior mediastinum via the cervical incision and a secondary approach via sternotomy for a full mediastinal exploration, in the event of an elusive offending gland. Interestingly the authors had stated, after an extensive literature search, that only a mere 597 total cases of hyperparathyroidism had been reported gloablly, since 1903 until circa 1950 (26).

McGeown et al (1959) recommended 4 gland exploration via the standard cervical exploration approach (BNE), coupled with a superior mediastinal exploration if an offending gland was not identified (27). A full mediastinal exploration via sternotomy was only advised as a re-operative strategy if no offending gland was identified upon initial exploration and the patient remained hyperparathyroid.

The Search for A Preoperative Localisation Study

Despite its effectiveness, cases requiring re-operation were still encountered, with the offending ectopic gland only discovered upon extensive search in known other possible ectopic locations (28). As a result, an endeavor to correctly identify these elusive glands prior to embarking on operative therapy was made, marking the birth of preoperative localisation. Originally, cine-oesophagography, selective venous sampling and arteriography were used from 1950 onwards with mostly poor results (29).

Doppman et al (1969) noted the inadequate and varied localisation rates with arteriography (0% to 66%) to be due to staining of both parathyroid tissue and overlying thyroid tissue as well as poor anatomic localisation in cases with no staining of any tissues (30). With some modification to the standard technique by combining selective inferior thyroid artery injections, anteroposterior and oblique projections, prolonged filming and routine subtraction, the best results achieved were localisations accurate in only 4 out of 9 patients.

Pre-operative ^{75}Se-selenomethionine scanning and preoperative injections of toluidine blue was assessed subsequently, with unimpressive results in the former and adverse cardiac effects in the latter (31,32). The use of ultrasonography (US) and computed tomography (CT) in preoperative localisation was subsequently described in the early 1970s, however in keeping with prior modalities, the sensitivities were poor (33,34).

The first rung on the evolutionary ladder of parathyroidectomy was described by *Roth et al* in 1975 and involved a unilateral neck exploration, whereby a single side of the neck was explored facilitating assessment of the 2 ipsilateral PG only (35). This technique was based on the rationale that in 80% of cases the cause of HPT is a single gland adenoma. The decision of the side to be explored was determined by either palpation of the neck, an oesophagogram, vascular sampling (venography or angiography) results or a guess.

This conservative parathyroidectomy revolution was supported by *Edis et al (1977)* and improved upon by *Tibblin et al (1982)* (36,37). The improvement entailed a modification of the conservative unilateral approach to involve an intra-operative saline float test & oil-red-O staining to discern between parathyroid adenoma and hyperplasia, the latter of which would then mandate further contra-lateral exploration. Although excellent cure rates were realised in the group with unilateral exploration, unfortunately far more patients who were intended for this technique upfront were subject to contra-lateral exploration, negating the intended benefit of a more conservative, strictly unilateral exploration. Therefore, a solution to address the difficulty in identifying pathological gland site/s was desperately needed.

The answer came in the form of drastic preoperative localisation advancements. Firstly, improvements in US technology and resultant superior accuracy rates were realised, as demonstrated by *Sample et al (1978)* and reaffirmed by numerous subsequent publications (38).

Edis et al (1979) demonstrated the use of high resolution US for parathyroid adenoma localisation in 10 patients (39). With the use of high resolution US, all parathyroid adenomas were accurately located. Despite the impressive results, the limitation of this study was the patient selection, as only patients with suspected large adenomas were included.

Duffy et al (1980) further demonstrated the immense benefit of high resolution US in preoperative localisation (40). The authors were able to correctly identify enlarged PG of greater than 5mm, from both primary and secondary HPT, in 19 of 22 patients translating to a accuracy of 83%.

Moreau et al (1981) & *Simeone et al (1981)* bolstered the effectiveness of high resolution US for preoperative localisation by demonstrating sensitivity rates for parathyroid adenomas of 93% and 87,5% respectively (41,42).

The benefit from these impressive improvements in US technology and accuracy rates were demonstrated by *Vogel et al (1998)* who assessed unilateral neck exploration compared to BNE between 1989 & 1996, with accurate US (90% accuracy) as a preoperative localisation method (43). They demonstrated equivalent cure rates, reduced operative time, reduced morbidity and improved cosmesis with the unilateral neck exploration, compared to BNE.

The second additional imaging advancement in parathyroid preoperative localisation was high resolution CT. This improvement in CT scanning was assessed in 1983 and demonstrated to be accurate, having achieved improved localisation rates of 76%, over the inferior 45% rates previously accomplished with conventional CT (44).

The most important step in parathyroidectomy innovation came with profound improvements in preoperative scintigraphic localisation. Parathyroid scintigraphy entails intravenous administration of a radio-labelled tracer coupled with the use of a gamma camera that reveals the anatomical location of the gland/structure in which the radio-labelled tracer concentrates. Originally in the early 1980s, Thallium 201 (^{201}TI) was used as a radiotracer for parathyroid scintigraphy, with poor results due to the rapid uptake and concentration of this tracer by the thyroid, in addition to the intended parathyroid tissue (45).

Additional radiotracers used include Iodine 123 (I^{123}) and Technetium 99m (^{99m}Tc) Pertechnate with mediocre results due to relatively modest uptake & washout and were demonstrated to be limited by the sizes and location of parathyroid adenomas (46).

The major breakthrough came by *Coakley et al (1989)* who described the Technetium 99m Sestamibi (^{99m}Tc Sesta-methoxyisobutylisonitrile) scan as a new form of preoperative localisation (47). The ^{99m}Tc Sestamibi (Sestamibi) showed increased parathyroid and thyroid uptake with slower washout, thus resulting in better delineation of the glands. Additionally, compared to ^{201}TI, it was demonstrated that this radiotracer had superior physical characteristics for the gamma camera imaging, with better image quality consequently.

Taillefer et al (1992) assessed Sestamibi in 23 patients with HPT, with subsequent cervical exploration revealing adenomas in 21 patients and parathyroid hyperplasia in 2 (48). Upon correlation, Sestamibi had correctly identified 19 of the 21 adenomas, therefore demonstrated an accuracy rate of 90% in preoperative localisation for patients with primary HPT.

Kwan et al (1993) compared ^{201}TI/pertechnate with Sestamibi. There were 27 cases performed with the ^{201}TI/pertechnate and 24 cases performed with Sestamibi (49). The accuracy rates were 77% and 95% respectively, demonstrating the superiority of Sestamibi.

This advancement allowed accurate preoperative localisation such that the single offending gland was identified allowing for a more targeted parathyroidectomy approach. A single miniature incision over the site of the offending gland, performed under a general or local anaesthetic, with deep dissection, followed by identification and excision of the pathological gland was possible, and so minimally invasive parathyroidectomy, also known as focused parathyroidectomy (FP), was born (50). This was revolutionary, as in theory, numerous benefits would be achieved over the standard of care, which was BNE, a well tried and tested method as demonstrated by the following authors.

Van Heerden et al (1991) reported their experience at the Mayo Clinic with 379 patients with primary HPT undergoing BNE (51). They demonstrated a cure rate of 99,5% with a morbidity and mortality of each less than 1%, advising a more liberal approach to cervical exploration.

Uden et al (1992) described their experience with BNE in 250 patients with primary HPT undergoing BNE (52). They demonstrated an overall cure rate of 98,8%, with no difference in the clinical and metabolic benefits from BNE in either older or younger patient groups.

Chen et al (1996) demonstrated significant improvements in cure rate and outcomes from BNE performed by an endocrine surgeon in a high-volume centre (53). They demonstrated a cure rate of 97%, with low morbidity, zero mortality and overall reduction in length of stay.

The Resistance To Change From The Gold Standard

Some authors, as demonstrated, continued to focus on their work with BNE, and not engage with the newly touted FP, however, there were other authors who were firmly against the notion of straying from the gold standard of BNE to the more attractive FP.

Delbridge et al (1998) assessed BNE in 733 patients with primary hyperparathyroidism (54). They achieved a cure rate of 99%, solidifying the success of this procedure. Remarkably, the authors stated the interest in 'minimal access' or unilateral parathyroid surgery was passing and misguided. They recommended avoiding these minimally invasive techniques as they believed there would be an inevitable increase in failure rates due to multi-gland disease (MGD), in exchange for a minimal cosmetic benefit. Additionally, the authors advised against routine preoperative localisation.

The Cost Issue Of FP

Some authors claimed the expense of additional preoperative localisation required to perform FP significantly adds to the overall costs, thus making this technique unfeasible.

Aarum et al (2007) compared 23 patients undergoing FP with preoperative localisation against 26 patients undergoing BNE, looking specifically at feasibility in terms of cost and cure (55). Cure rates were similar at 96% and 94% respectively, however the authors demonstrated FP to be 21% more costly due to the requisite preoperative localisation studies

Slepavicius et al (2008) in their prospective randomised blinded trial compared 23 patients undergoing BNE to 24 patients undergoing FP (56). The authors revealed both techniques to be safe and effective, with FP showing numerous advantages, however they also demonstrated greater costs associated with FP.

Baliski et al (2008) compared the 'gold standard' BNE to minimally invasive parathyroidectomy in terms of cost (57). They demonstrated BNE to have the lowest cost associated, with excellent cure rates in return.

Additionally, some authors claimed that FP was associated with inferior cure rates and increased recurrence rates.

Delbridge et al (2000) reported on their experience with FP in 50 patients (58). Only 42 patients of the 50 undergoing FP were cured, translating to a cure rate of 84%. Of the remaining 8 patients, 7 required conversion to BNE and 1 was a failed procure. The authors concluded that although FP may have been feasible, there were concerns associated.

Norman et al (2012) reported their experience with 15000 parathyroidectomies, comparing BNE with FP (59). They demonstrated FP to be associated with a higher recurrence rate, with a 1 year recurrence rate of 3% – 5% and a 10 year recurrence rate of 4% - 6%.

Eventually, through the next 2 decades, articles subsequently demonstrated FP to be equally effective as BNE in terms of cure, with reduced overall cost, mostly stemming from markedly reduced operative time and hospital stay and reduced morbidity, confirming this technique to be safe and feasible (60).

Udelsman et al (2000) revealed the immense benefits of FP for primary HPT (61). They revealed their experience with 100 cases of minimally invasive parathyroidectomy, with a cure rate of 100%, reduced hospital costs and no long term complications.

Burkey et al (2003) reported on their experience with 100 parathyroidectomies, 70 cases of FP and 30 cases of BNE (62). Both methods of parathyroidectomy resulted in an overall 100%, cure, however FP was demonstrated to be superior to BNE, with reduced operative time, reduced length of hospital stay, reduced morbidity and resulted in rapid convalescence.

Pang et al (2007) described their experience with 500 cases of consecutive FP compared to 601 cases of BNE over a 5 year period (63). They demonstrated FP to be safe and effective, with a cure rate of 97,4% with no evidence of any increase in morbidity, compared to BNE (3% vs 3,99%).

Udelsman et al (2002) subsequently compared 255 cases of minimally invasive parathyroidectomy to 401cases of BNE (13). The authors demonstrated equivalent cure rates, with FP associated with reduced morbidity (1,2% vs 3% respectively), 50% reduced operative time, a seven-fold reduction in length of hospital stay and a nearly 50% reduction in cost, compared to BNE.

Norlen et al (2015) assessed outcomes of parathyroidectomies in 4569 patients, of which 2531 underwent FP and 2038 underwent BNE (64). The authors demonstrated FP to have an equivalent long term recurrence rate to BNE (0,6% vs 0,4% respectively), with significantly reduced morbidity (3,6% vs 7,6%).

Udelsman et al (*2011)* ultimately described their final cumulative experience with minimally invasive parathyroidectomy (65). Overall they compared 1037 cases of FP to 613 cases of BNE. The authors demonstrated a higher cure rate with FP (99,4%) compared to BNE (97,1%), with reduced morbidity, length of stay and cost, concluding FP to be the superior technique.

Wong et al (2011) discussed their experience with 100 parathyroidectomy cases. 93 underwent FP and 7 underwent BNE (conversions from FP) (66). The operative time for FP was significantly lower than for BNE, with an excellent overall cure rate of 96%.

Sestamibi Scans

The improvements in FP results were mostly due to the marked improvements in Sestamibi. Sestamibi originally made use of planar 2D images, however, further advancements were realised with the advent of the single photon emission computed tomography (SPECT) which, when used in combination with the Sestamibi (Sestamibi SPECT), produced detailed 3D images resulting in improved accuracy rates. The combination of CT to Sestamibi SPECT (Sestamibi SPECT/CT) produced 3D images with anatomical detail and with the addition of intravenous contrast during the CT (termed 4D CT), exquisitely detailed anatomical images were produced (67,68).

Wong et al (2015) in their meta-analysis of 24 studies over 10 years assessed Sestamibi, Sestamibi SPECT and Sestamibi SPECT/CT as preoperative localisation modalities with a focus on their sensitivities (69). They demonstrated an incremental improvement in sensitivities from the original Sestamibi, to Sestamibi SPECT and finally the best sensitivity with Sestamibi SPECT/CT.

Yeh et al (2019) assessed 400 patients with 4D CT, Sestamibi SPECT/CT and both modalities combined as forms of preoperative localisation (70). They demonstrated 4D CT to have the highest sensitivity, superior to Sestamibi SPECT/CT. Additionally, the combination of both did not improve the sensitivity.

Multiple Gland Disease (MGD)

Despite excellent preoperative localisation accuracy and exceptional cure rates realised with FP, the hindrance of MGD and missed double adenomas remained a challenge. The incidence of MGD is estimated to be between 10% - 15% (71).

Lee et al (2002) demonstrated their experience with MGD (72). The authors assessed 214 consecutive cases of BNE and compared this to 2166 cases of BNE and 2095 cases of FP reported in the literature. They found a 20,6% incidence of MGD in their cohort, a 19,3% incidence of MGD in the literature from BNE and a 5,3% incidence of MGD reported with FP in the literature. They concluded the concern of missed cases of MGD with FP was evident from the low rate of MGD reported with FP in the literature.

Gough et al (2006) assessed 50 patients requiring re-operative parathyroid surgery (73). The authors demonstrated 62% of cases of persistent or recurrent primary HPT requiring re-operation was due to MGD. Additionally, they also revealed the poor sensitivity of preoperative localisation for MGD.

Siperstein et al (2008) performed BNE in all patients having had FP in their series and demonstrated missed MGD in 22% of patients with Sestamibi as preoperative localisation, in 22% when US was used and in 20% of cases when combined Sestamibi and US were used as preoperative localisation (74).

The issue stems from the fact that preoperative localisation with US and Sestamibi is accurate for single gland disease, and has shown to be poorly sensitive for multi-gland disease (75). With Sestamibi, it is thought the inaccuracy with identifying the second adenoma in MGD results from the majority of radio-labelled tracer being concentrated in the first adenoma encountered, concealing the second. As a consequence, a FP in one of these patients with an unidentified second adenoma will result in inadequate cure, necessitating re-localisation and re-operation.

Nichols et al (2012) assessed 651 patients with primary HPT, 80% with single gland disease and 20% with MGD (76). Sestamibi was demonstrated to be significantly less sensitive for MGD compared to single gland disease (61% vs 97%).

Milas et al (2003) reviewed 828 patients with HPT undergoing BNE (77). They discovered MGD in 28% of patients and single gland disease in 71% of patients. Sestamibi correctly identified MGD in only 6% of patients, with the authors concluding FP, as opposed to BNE, may predispose to cases of persistent or recurrent HPT.

Intraoperative Parathyroid Hormone (IOPTH) Assay

Fortuitously, the quick PTH, also known as the intraoperative parathyroid hormone (IOPTH) assay, was conceived. This is a chemiluminometric assay with rapid turnover in sample processing that bears results within a mere 15 – 20 minutes, allowing for intraoperative use. The utility in the test lies in its predictive power, whereby a 50% or greater drop in IOPTH, relative to baseline PTH, serves as confirmation of successful excision. A drop of less than 50% indicates additional PG pathology such as multi-gland disease, which would then necessitate a BNE to identify the additional elusive offending gland (78).

Nussbaum et al (1988) originally described the use of IOPTH, with a modification of the standard PTH testing by immunoradiometric assay (IRMA), producing a result within 15 minutes (79). The authors were able to demonstrate an IOPTH level fall to less than 40% of baseline PTH, from a 15 minute post excision sample, correlated with successful parathyroidectomy.

Ryan et al (1990) subsequently described their version of IOPTH, using IRMA with differing incubation methods (80). The result was a test with wider reference range, specifically a lesser lower limit, however with a turnaround time of 1 hour. They demonstrated an IOPTH sampled at 20 minutes post excision correlated to complete excision.

Irvin et al (1991) described their experience with IOPTH to assist surgeons with parathyroidectomies in an endeavour to improve cure rates by reducing the incidence of missed(MGD) (81). The authors used the IRMA modified IOPTH with an alteration to the incubation time, allowing a 15 minute turnaround. The issue encountered was the accuracy of the IOPTH being affected by PG manipulation. They discovered elevated level of IOPTH prior to excision, after manipulation alone. They concluded this form of IOPTH should rather be relative to post-manipulation, pre-excision PTH levels, rather than baseline PTH levels, to boost accuracy.

Irvin et al (1993) reported on their improved experience with IOPTH (82). The authors further modified the IRMA processing such that the IOPTH turnaround time reduced to 12 minutes. Additionally, accuracy was markedly improved. A 10 minute post excision IOPTH drop of 54% correlated with successful parathyroidectomy, and was associated with an overall accuracy of 97%.

Irvin et al (1994) described their up-to-date experience with IOPTH (83). Sampling PTH 5 minutes post excision, and processing the specimen with immunochemiluminometric assay (ICMA) rather than the traditional IRMA resulted in a sensitive test with rapid turnaround time of 10 minutes, which allowed intraoperative use to confirm completeness of resection. The authors demonstrated the sensitivity of this test to predict postoperative calcium levels of 94% and an overall accuracy of 95%.

Over the next few decades, numerous studies were published on IOPTH use for parathyroidectomy, with initial studies revealing marked improvements in cure rates, recommending this procedure be routine with all FP, to some later studies revealing no difference in cure with or without the IOPTH.

Quinn et al (2021) in their systematic review and meta-analysis assessed 12 studies describing FP with IOPTH for primary HPT (84). The authors revealed IOPTH to be of great benefit, with increased cure rates, reduced recurrence and need for re-operative surgery, increased conversion from FP to BNE from positive IOPTH results and no statistical increase in operative time. Additionally, the converse was found true. FP without IOPTH resulted in less conversions from FP to BNE, reduced cure rates and increased re-operative surgery for recurrence.

Ishii et al (2018) in their systematic review and meta-analysis assessed 14 studies describing FP with IOPTH for primary HPT (85). The authors revealed higher cure rates for FP without the use of IOPTH compared to FP with IOPTH (99,3% vs 98,1%) and lower recurrence rates without IOPTH (0,2% vs 1,5%). The concluding remark was that FP is a safe and effective procedure with concordant preoperative imaging, without the need of IOPTH.

The numerous publications on IOPTH revealed marked variation in sampling and interpretation, giving rise to differing cure rates and so differing opinions on utility. This dilemma required some stricter criteria to create uniformity.

The *Halle Criterion* published recommended a low normal IOPTH level (≤35 ng/L) within 15 minutes post excision of the offending PG serving as confirmation of a successful procedure. The *Miami Criterion* recommended a 50% drop in IOPTH relative to preoperative baseline or pre-excision levels, sampled at 10 minutes post excision, serving as confirmation of success. The *Rome Criterion* recommended an IOPTH of greater than 50% drop relative to the highest pre-excision levels and/or IOPTH within the reference range at 20 minutes post excision and/or an IOPTH level of 7.5 ng/L or less than the 10 minutes post excision value. The *Vienna Criterion* recommended an IOPTH level drop of greater than 50% relative to baseline PTH levels. The *Miami Criterion* has demonstrated the highest accuracy and sensitivity rates (86).

The latest National Institute of Clinical Excellence (NICE) guidelines for primary HPT management recommend against routine IOPTH use during primary surgery due to minimal benefit and potential additional cost involved. The latest European Society of Endocrine Surgeons (ESES) guidelines for primary HPT management differ from the NICE guidelines. The ESES recommends IOPTH use for the primary surgery in instances of discordant preoperative localisation or when only single imaging is used as preoperative localisation (87).

Minimally Invasive Radio-Guided FP (MIRP)

Other intraoperative adjuncts have been described. *Norman et al (1999)* proposed the minimally invasive radio-guided FP (MIRP) whereby a radioactive tracer that concentrates in parathyroid tissue is injected preoperatively and serves as an intraoperative road map (88). Once in theatre, a handheld gamma probe is used to detect radioactivity which is present in the parathyroid tissue from the radioactive tracer. Once the offending gland is excised, the gamma probe is applied to excised gland and the neck. A confirmatory result of successful excision is an excised gland of 20% or more radioactivity and a background radioactivity of less than 20% in the neck. Any lower reading from the PG or higher neck background radioactivity reading indicates potential residual parathyroid tissue and thus further exploration is warranted. However this method was not reproduced in any other centres.

Methylene Blue For Localisation

Methylene blue use for rapid intraoperative identification of the PG was originally described by *Dudley et al (1971)* (89). It has been shown by *Patel et al (2012)* in a systematic review of 39 studies that methylene blue is effective for rapid intraoperative PG identification (90). The dye is administered intravenously and subsequently concentrates and stains the PG, allowing for easy identification. However, despite the impressive results reported, the studies included in the systematic review were all observational studies of low quality evidence. There is no randomised controlled trial or other high quality evidence supporting its use. Additionally, the great deterrent with using this technique is the grave adverse effects. Numerous studies have demonstrated severe neurotoxicity associated with this technique (91,92).

Candell et al (2014) described their experience with intraoperative US guided methylene blue dye injection into the PG for re-operative parathyroid surgery (93). They demonstrated immense benefit with this technique in assisting PG identification in an already 'hostile' field. Cure was achieved in all but 1 patient with parathyroid carcinoma who developed recurrent hypercalcaemia. The complication rate was low, with 1 case of transient recurrent laryngeal nerve palsy.

Frozen Section

Frozen section examination refers to the freezing and sectioning of intraoperative specimen with subsequent rapid microscopic pathological examination to provide swift intraoperative feedback to the operating surgeon (94). The benefit is the rapid turnaround time, however this is at the expense of accuracy. Currently its routine use is not recommended for parathyroid surgery. The benefit it confers is identification of parathyroid tissue over other tissue types, however is not able to distinguish between a parathyroid adenoma and parathyroid hyperplasia. Additionally, there have been cases of missed diagnoses due to inaccurate frozen section results. Since the advent of IOPTH, the reliance on frozen section for parathyroid surgery has declined (95,96).

Newer Intra-Operative Adjuncts

A multitude of additional intraoperative adjuncts to assist in PG identification in the form of optical techniques have been published within the last 5 years. The majority of clinical studies have evaluated autofluorescence and indocyanine green with good results thus far, however more rigorous evidence with randomised controlled trials is warranted to truly validate their benefit (97).

Minimally Invasive Video Assisted Parathyroidectomy (MIVAP)

As a result of the impressive performance of FP and its subsequent general adoption, much effort has been made to perfect FP even further, with numerous evolutions. Originally, FP, like BNE, has been performed as an 'open' procedure only, involving a skin incision and followed by deep dissection and PG excision. Newer minimally invasive techniques have been applied to FP with the use of an endoscope.

Minimally invasive video assisted parathyroidectomy (MIVAP) first described by *Miccoli et al (1997)* involves a targeted miniature skin incision (via either a central or lateral approach) followed by open dissection with subsequent insertion of an endoscope to facilitate accurate

PG identification and excision (98,99). This technique relies on external traction to create a working room, with no insufflation whatsoever. Results have shown equivalent operative time, cure rates and length of hospital stay to the traditional open technique (100).

Barczynski et al (2006) in their randomised blinded trial compared traditional open FP to MIVAP and demonstrated equivalent cure and morbidity, however MIVAP was associated with lower postoperative pain requiring reduced analgesic usage; improved convalescence, and better cosmesis with the disadvantage of increased cost from endoscopic instrument use, when compared to open FP (101).

The purely endoscopic parathyroidectomy (EP) was first described by *Gagner et al (1996)* and entails a skin incision followed by endoscope insertion, insufflation and dissection (102). Two access options exist, central and lateral. The central access technique, performed entirely endoscopically, is best used for anteriorly located PG. For deep, posteriorly located PG, a lateral approach to EP, as described by *Henry et al (1999),* is better suited (103,104). The overall concern with this technique is the conversion rate. *Fouquet et al (2010)* demonstrated excellent cure rates (98%), however 28% of cases had to be converted to the open procedure due to lack of intraoperative localisation; bleeding; inadequate IOPTH drop and difficult dissection (105). The authors conclude that this may be the reason this technique has not been widely adopted.

Problem Statement

Parathyroidectomy from primary HPT has undergone substantial evolutionary change over the past 98 years. FP has been demonstrated to be safe, effective and cost friendly and is the current standard of care. However, these recommendations stem from literature emanating from high-income countries

Research Question

It remains to be demonstrated as to whether FP is safe and cost effective in low and middle-income countries, considering the resource constraints these regions face.

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Part 2 Submission ready manuscript

FEASABILITY OF FOCUSED PARATHYROIDECTOMY IN DEVELOPING COUNTRIES – A Scoping Review

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Abstract

Background

The mainstay of treatment of primary hyperparathyroidism (HPT) involves a parathyroidectomy, which, depending on the number of affected parathyroid glands and the availability of resources, may involve a bilateral neck exploration (BNE) with 4 gland assessment or a minimally invasive, focused parathyroidectomy (FP) necessitating pre-operative localisation.

Objective

We assess the feasibility of FP, in developing countries where limited resources may impede its use based on the potential lack of availability and or cost of these radiological studies and biochemical tests.

Methods

A scoping review was performed with published literature evaluated from the past 15 years (2007 & onwards). Articles were screened and only included if they discussed focused parathyroidectomy, preoperative localisation, economic impact and they originated from a developing country (upper middle or lower middle-income).

Results

A total of 18 articles met the inclusion criteria, comprising 7 developing countries (2 upper middle-income and 5 lower middle-income countries). Preoperative localisation was performed in all studies, with overall accuracy rates of 75,5% for ultrasound and 85,7% for ^{99m}Tc Sestamibi. A total 1202 patients (70%) had FP. Five hundred and fifty-five patients underwent FP without intraoperative adjuncts and 647 underwent FP with intraoperative adjuncts, with cure rates of 95,4% and 97,8% respectively. Overall cure rate for FP was 96,6%.

Conclusion

With access to accurate preoperative localisation and excellent cure rates with and without intraoperative adjuncts, we conclude that FP is feasible in developing countries.

Background

The 'gold standard' operative treatment of primary HPT has been BNE since the first parathyroidectomy in 1925, with excellent cure rates of greater than 95% demonstrated (1). The rationale at the time, was the knowledge of multi-gland disease coupled with the inability to identify specific diseased glands preoperatively. *Van Heerden et al (1991)* demonstrated a cure rate of 99,5% in 379 patients with primary HPT undergoing BNE (2). Consistently high success rates were further demonstrated by multiple authors, revealing this procedure to be reliable and easily reproducible (3, 4).

The FP was conceived due to the realisation that in 80% of cases of primary HPT the aetiology is a single gland adenoma, allowing a more targeted approach to parathyroidectomy (5). However, FP is naturally entirely reliant on adequate preoperative localisation. The greatest advancement being the ^{99m}Technetium Sestamibi, as described by *Coakley et al (1989)* (6). Today, there are numerous preoperative localisation studies available viz different types of Setambibi radionucleotide scans, CT scans, MRI scans and ultrasound (US), each with varying degrees of sensitivities.

Initially, certain authors were firmly against the notion of FP, with some advising against the technique as they simply considered it to be a passing trend and misguided (7). They identified 2 main concerns with this technique.

The first was that of inferior cure rates. FP was highlighted by *Delbridge et al (2000)*, who assessed FP in 50 patients and demonstrated an inferior 84% cure rate with FP, significantly lower compared to the standard of care BNE's established 95% cure rate (8). These inferior cure rates were mostly due to "double adenomas" which can account for up to 10% of all parathyroid adenomas (9). However, since then, intraoperative adjuncts used during parathyroidectomy evolved significantly, with intraoperative nuclear scanning and rapid PTH test (IOPTH) cure rates equalled that of BNE (10,11). When coupled with intraoperative assays, it also obviates inspection of the remaining PG's thus preventing the complications associated with it like those that accompany BNE.

The second concern with FP was the cost, with a some authors demonstrating a higher cost associated with FP compared to BNE, resulting from the requisite preoperative localisation tests and the addition of intraoperative adjuncts (12, 13). However, since then, the cost of previously elusive preoperative localisation studies decreased, and the literature reflected this by subsequently revealing FP to be cost effective comparative to BNE alone, balanced by the added cost of increased operative time & longer hospitalisation associated with the latter (14).

Subsequently, FP has been shown to be superior to BNE. *Udelsman et al* in 2000 with 100 cases, in 2002 with 255 cases and in 2011 with 1037 cases of FP demonstrated a higher cure rate with FP (99,4% vs 97,1% with BNE) with reduced cost, morbidity and length of hospital stay (15-17). Numerous other authors have demonstrated consistent findings (18-20).The benefits of FP over traditional BNE include equivalent rates of cure (95 – 98%), with added benefits of: the ability to be performed under a local anaesthetic; outpatient recovery; shorter operative time; desirable cosmesis; reduced nerve injuries and elimination of permanent hypoparathyroidism (21). Thus, in the setting of positive preoperative localisation, FP has become the new standard of care.

Importantly, however, the mounds of literature we are guided by emanate from the developed, 'high-income world', where resources are far more abundant, with remarkable strides made in healthcare resource allocation. Unfortunately, in a developing (middle-income) setting, with marked disparity between the private and public healthcare sector, resources are drastically limited, often to the point of tailoring guideline recommendations to local resource availability (23).

Therefore, despite the described cost-effectiveness of FP with requisite localisation & IOPTH in studies from developed world literature, a developing country may not be able to rationalise this cost. In addition to the cost, availability is a concern, which, when considered, would drastically affect the feasibility of this procedure, over a traditional BNE that requires no additional localization or intra-operative adjuncts.

Objective

This scoping review serves to ascertain the feasibility of FP in developing countries, considering the additional cost and unclear availability of mandatory preoperative localisation studies along with requisite intraoperative adjuncts and the necessary skill and experience needed to facilitate this procedure successfully.

Methods

This scoping review evaluated primary, secondary and tertiary literature, drawing from both published peer-reviewed and grey literature. The framework guide laid out by *Arksey & O'Malley (2005),* including modifications published by *Levac et al (2010),* were followed (24,25). The suggested stages traversed include: 1. identifying the research question; 2. identifying the relevant studies; 3. study selection, with specified inclusion and exclusion criteria; 4. charting the data and lastly 5. collating, summarising and reporting the results. Primarily, the PRISMA-Scr extension framework and checklist was adhered to, with reporting of eligible studies via the PRISMA flow diagram The eligibility of the research question was explored via the PCC framework (26).

<u>Eligibility of Research Question</u>

The PCC framework – namely; 'population, concept and context' framework, as recommended by the Joanna Briggs Institue (JBI), was employed (27). The population was identified as primary hyperparathyroid patients warranting parathyroidectomy. The concept was identified as cost and availability accounting for feasibility of focused parathyroidectomy comparative to bilateral neck exploration in developing countries. Finally, context was identified as developing countries.

Search Criteria

An extensive literature search was conducted, using Boolean logic operators such as 'AND' & 'OR', with the following key terms: 'primary hyperparathyroidism', 'parathyroidectomy', 'surgery', 'nuclear medicine', 'developing countries', 'cost' and 'South Africa'. The keywords used complied with Medical Subject Headings (MeSH) terms, adjoined with relevant subheadings & qualifiers, falling within the jurisdictions of the MeSH tree structures. To broaden the exposure to relevant articles, the following non-MeSH conforming keywords were additionally employed: 'focused parathyroidectomy', 'feasibility', 'low-income', 'economic viability', 'Sestamibi' and 'intra-operative PTH'.

Screening

Articles were retrieved upon exploration of the literature via the aforementioned library databases. Screening was initiated firstly by means of confirming relevance based on review of each title of the studies retrieved. Thereafter, abstracts were scanned, followed by introductions and statements of purpose. If the studies fulfilled the purpose of this review, the countries of origin were then scrutinized and cross checked with the United Nations Development Program (UNDP) & World Bank (WB) list of developing/middle income countries to ensure the articles to be perused were relevant (28,29). Finally, the full texts were engaged.

Eligibility Criteria

Inclusion Criteria

The basis for which these studies were selected includes: 1. studies providing evidence on surgical management of primary hyperthyroidism, specifically discussing focused or minimally invasive parathyroidectomy; 2. studies providing evidence on preoperative localisation; 3. studies providing evidence on a developing world approach to parathyroidectomy; and 4. studies providing evidence on economic burden of either parathyroidectomy option. The period explored was literature from the past 15 years (from 2007 onward). No restriction on language was employed, allowing for greater acquaintance.

Exclusion Criteria

Studies not meeting the inclusion criteria of: providing evidence on surgical management of primary hyperthyroidism; with specific discussion on focused/minimally invasive parathyroidectomy; providing evidence on preoperative localization; providing evidence on a developing world approach to parathyroidectomy and providing evidence on economic burden of either parathyroidectomy option were all excluded, including all studies published prior to 2007.

Results

A total of 940 relevant articles were encountered upon exploration of the literature from 8 different databases *(see Table 1*: **Evidence Sources***)*. After duplicates were removed and elimination by screening of article titles, abstracts, full texts and countries of origin, a total of 18 remaining articles fulfilled the purpose of this review and thus were included for study *(see Figure 1* **PRISMA Flow Chart of Included Studies***)*.

In the 18 articles, a total 1716 patients underwent parathyroidectomy from 7 developing countries (5 studies from South Africa (upper middle-income); 5 studies from India (lower middle-income); 3 studies from Pakistan (lower middle-income); 2 studies from Turkey (upper middle-income); 1 study from Egypt (lower middle-income); 1 study from Algeria (lower middle-income and 1 study from Nigeria (lower middle-income). *(see Table 2*: **Characteristics of Studies***)*.

FP was performed in 1202 patients (70%) with 7 studies (38,9%) reporting on 647 patients having had FP with intraoperative adjuncts (including IOPTH, methylene blue, frozen section or the gamma probe) and 11 studies (61,1%) reporting on 555 patients having had FP without intra-operative adjuncts.

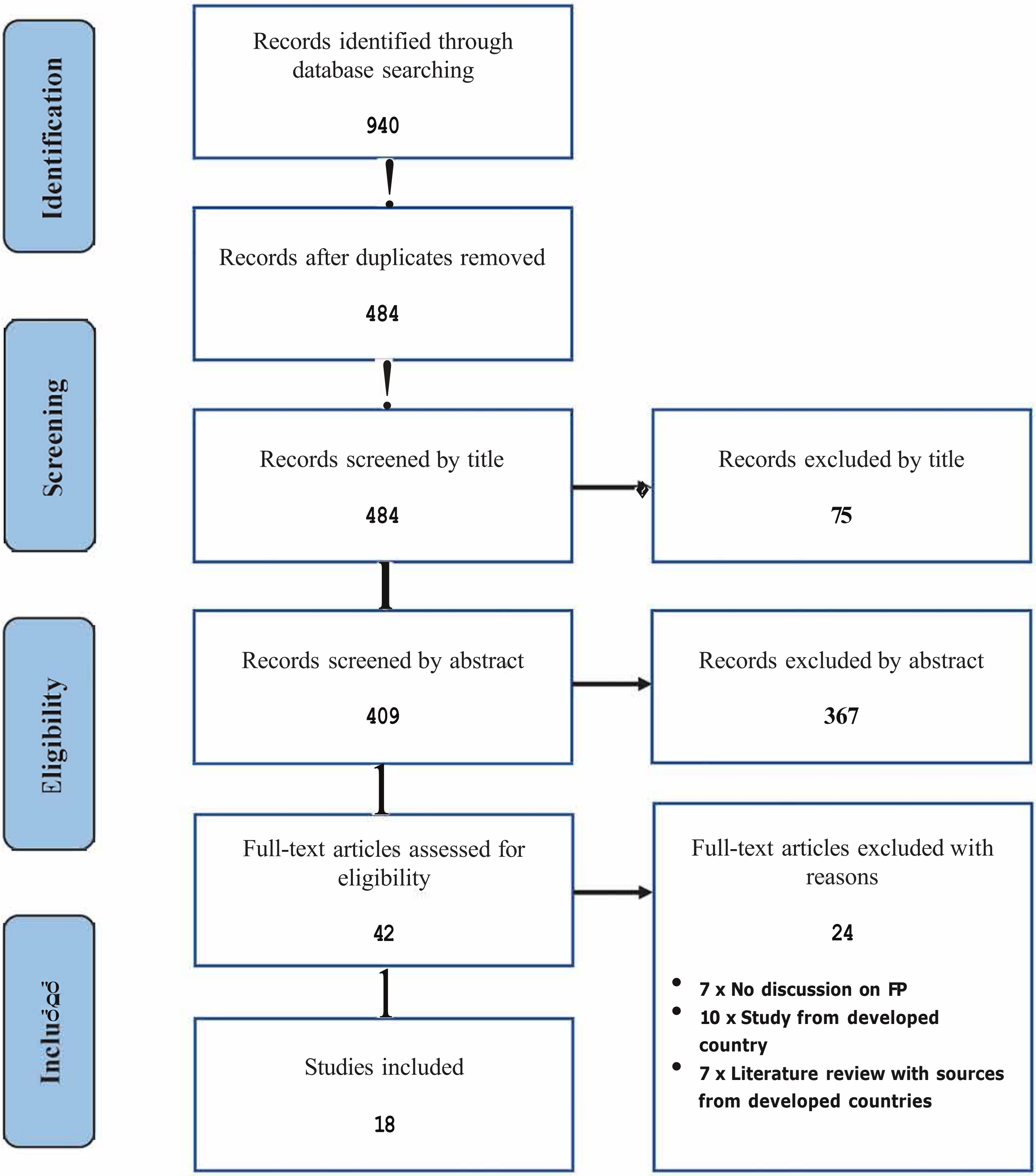
Cure rates from the studies included in this review for FP were reported for 15 (7 with intraoperative adjuncts & 8 without intraoperative adjuncts) of the 18 studies, ranging from 83,3% to 100%, with an overall cure rate of 96,6%. Below is a table detailing FP with/without intraoperative adjuncts and cure rates. (s*ee Table 3*: **Cure Rates**)

Preoperative localisation in these developing countries were performed by US and ^{99m}Tc Sestamibi, with 1 study describing the use of C11 methionine PET/CT as an additional localisation modality. Accuracy rates of localisation studies in these developing countries ranged from; 44% - 94% with US, 66,5% - 100% with ^{99m}Tc Sestamibi and 71,4% for the C11 methionine PET/CT.

Table 1: Evidence Sources

Database	No. of Studies Encountered
Pubmed	446
Google Scholar	217
ProQuest	132
Science Direct	61
WorldCat	39
Academic Search Complete	32
Sabinet	7
Langenbeck's Archive of Surgery	6
Total	940

Figure 1 PRISMA Flow Chart of Included Studies



(30)

Table 2: Characteristics of Studies

Scoping Review Data Collection Tool								
	Author	**Title**	**Year**	**Country & UNDP/WB Classification(31)**	**Study Type**	**No. of Patients**	**Main Outcomes**	**Ref**
1	Usta et al	A 20-Year Study on 190 Patients With Primary Hyperparathyroidism in a Developing Country: Turkey Experience	2015	Turkey (Developing/Upper-Middle Income Country)	Retrospective descriptive study	190	Preoperative localisation accuracy rate by US & ^{99m}TcS was 82,6%, and 89,4% respectively. Combined ^{99m}TcS & US yielded a 92% localisation accuracy rate. FP with intraoperative frozen section analysis only was performed in 167 patients and resulted in good cure rate of 99,52% - similar cure rate to BNE, with significantly decreased operative time, hospital stay & hospital cost.	(32)
2	Siddiqui et al	Changing paradigms in the surgical management of hyperparathyroidism at a tertiary care hospital in a developing country	2019	Pakistan (Developing/Lower-Middle Income Country)	Retrospective study	72	Preoperative localisation accuracy rate by US & ^{99m}TcS was 71,1%, and 90,1% respectively. FP without intraoperative adjuncts, was performed in 27 of the total 72 cases with a cure rate of 92,6%, similar cure rate of BNE (90,5%) with fewer complications - demonstrating this technique to be both effective & reasonable.	(33)
3	Paruk et al	Characteristics, management and outcome of primary hyperparathyroidism in South Africa: a single-centre experience	2013	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	28	Preoperative localisation was only performed with ^{99m}TcS, with an accuracy rate of 93,7%. FP without IOPTH monitoring was performed in 19 of 28 patients, with a cure rate of 94,7%. Demonstrating the safety & feasibility of this technique	(34)
4	Mallikarjuna et al.	Five-year Retrospective Study on Primary Hyperparathyroidism in South India: Emerging Roles of Minimally Invasive Parathyroidectomy and Preoperative Localization with Methionine Positron Emission Tomography-Computed Tomography Scan	2018	India (Developing/Lower-Middle Income Country)	Retrospective study	54	Preoperative localisation accuracy rate by US & ^{99m}TcS was 72,2%, and 70,6% respectively. Additionally, C11 methionine PET was used for localisation in a portion of patients, with an accuracy rate of 71,4%. 43 patients underwent FP without intraoperative adjuncts, more than three-quarters (79.6%) of the total patients during the 5 year period, demonstrating this technique to be feasible in this locality of South India. No cure rate was reported.	(35)
5	El-Hady et al.	Focused parathyroidectomy for single parathyroid adenoma: a clinical account of 20 patients	2018	Egypt (Developing/Lower-Middle Income Country)	Prospective Analysis	20	Preoperative localisation accuracy rate by US & ^{99m}TcS was 75%, and 90% respectively. Combined ^{99m}TcS & US yielded a localisation accuracy rate of 95% in this setting. FP without IOPTH monitoring was performed in 19 of 20 patients, with a cure rate of 95% & no major complications reported, with the	(36)

							authors concluding this technique to be safe and feasibility, even without intra-operative adjuncts.	
6	Sen et al	Focused Parathyroidectomy Under Local Anesthesia – A Feasibility Study	2019	India (Developing/Lower -Middle Income Country)	Prospective Analysis	65	Preoperative localisation was performed by US & ^{99m}TcS, however the accuracy rate was not determined in this study as only patients with 100% concordance with pre-operative localisation were included in this study. FP without IOPTH monitoring was performed in 48 of 65 patients. 30 of the 48 cases were performed under local anaesthetic, with significantly reduced cost demonstrated and a cure rate of 100% reported, concluding this procedure to be safe and feasible.	(37)
7	Rawat et al	Minimally Invasive Parathyroidectomy as the Surgical Management of Single Parathyroid Adenomas: A Tertiary Care Experience	2022	India (Developing/Lower -Middle Income Country)	Prospective Analysis	116	Preoperative localisation accuracy rate by US & ^{99m}TcS was 93.10%, and 96.55% respectively. Combined ^{99m}TcS & US yielded a localisation accuracy rate of 100% in this study. FP with IOPTH monitoring was performed in all patients with a cure rate of 99,13% reported, with the authors concluding this procedure to be safe and feasible.	(38)
8	Zitouni et al	Monocentric experience of primary hyperparathyroidism surgery in Algeria	2021	Algeria (Developing/Lower -Middle Income Country)	Retrospective study	62	Preoperative localisation accuracy rate by US & ^{99m}TcS was 60,7%, and 66.5% respectively. Combined ^{99m}TcS & US accuracy rate was 100% in this study. 28 of 62 patients had MIP (unilateral exploration + focused), 18 of whom specifically had a FP without IOPTH monitoring, with a cure rate of 83,3% - demonstrating the safety & feasibility of this procedure.	(39)
9	Van Wyngaard et al	Pre operative localisation and surgical outcomes for Primary Hyperparathyroidism (PHPT): an 11 year review at a South African hospital	2018	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	98	Preoperative localisation accuracy rate by US & ^{99m}TcS was 44%, and 75% respectively. FP with IOPTH monitoring was performed in 76% of patients [75 patients] with the remaining 24% having had BNE. The overall cure rate was 94%. This study demonstrates the safety and feasibility of FP.	(40)
10	MacRobert et al	Single gland versus multigland disease in primary hyperparathyroidism at the Wits Donald Gordon Medical Centre in Johannesburg, South Africa	2021	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	252	Preoperative localisation accuracy rate by US & ^{99m}TcS for single gland disease was 77,1%, and 72,9% respectively, Combined ^{99m}TcS & US yielded a sensitivity of 79.7% for single gland disease. FP was performed in 44.8% of patients [113 patients] with no documented use of intraoperative adjuncts, with the remaining having had BNE. No cure rate was established due to lack of 6-month postoperative results. This study re-enforced the notion that BNE is the gold standard, however, with a predominance of single gland disease (83,3%), this study advocates equally for FP and BNE.	(41)

11	Olatoke et al	Serial pathologic fractures of five long bones on four separate occasions in a patient with primary hyperparathyroidism, challenges of management in a developing country: a case report	2013	Nigeria (Developing/Lower -Middle Income Country)	Case Report	1	In this case report, the parathyroid adenoma was successfully localised with combined US and ^{99m}TcS. Despite numerous challenges such as the ^{99m}TcS facility being 250km away and PTH testing needing to be done in another African country, the Authors persisted and were able to perform a focused unilateral exploration, with a demonstrated drop in postoperative PTH levels. This case report demonstrates while it may be possible to perform a parathyroidectomy in this country, with PTH needing to be performed in another country and the distance of travel required for pre-operative localisation, there are significant challenges associated with both BNE & FP.	(42)
12	Bombil et al	Sonar guided focused parathyroidectomy under cervical block	2018	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	15	This study looked specifically at FP performed under a cervical block +/- local anaesthetic. Although no exact rate was provided, combined US and ^{99m}TcS was used for preoperative localisation, with a report of good localisation/concordance, and mention of only one discordant finding. 100% of patients had a FP with complete resolution of hypercalcaemia in all patients, demonstrating this surgical technique to be safe and feasible.	(43)
13	Yadav et al	Surgical Management of Primary Hyperparathyroidism in the Era of Focused Parathyroidectomy. A Study in Tertiary Referral Centre of North India	2019	India (Developing/Lower -Middle Income Country)	Retrospective study	373	Preoperative localisation accuracy rate by US & ^{99m}TcS was 80%, and 86% respectively. FP was performed in 49,32% of patients [184 patients], with IOPTH monitoring being performed in 85% of FP cases [151patients] and 66.21% of total cases [247]. There was no statistical difference in cure with (98,02%) or without IOPTH (100%). An overall cure rate of 97,8% was reported, with a cure rate of 98,92% for FP, statistically similar to that of BNE, with the authors concluding FP to be safe and feasible, with or without IOPTH monitoring.	(44)
14	Dahiya et al	Surgical outcome after focused parathyroidectomy: experience from a tertiary care centre in North India	2021	India (Developing/Lower -Middle Income Country)	Retrospective study	192	Preoperative localisation accuracy rate by US & ^{99m}TcS was 83%, and 88% respectively. FP without IOPTH was performed in all 192 patients, with a cure rate of 97,92%. The authors conclude the technique to be the treatment of choice for sporadic primary HPT, when there is accurate pre-operative localisation, thus demonstrating the safety and feasibility of this technique.	(45)

15	Alikor et al.	The Usefulness of ^{99m}technetium-sestamibi Parathyroid Scintigraphy in Preoperative Localization of Parathyroid Adenoma in Patients with Primary Hyperparathyroidism at an Academic Hospital in South Africa	2017	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	11	Preoperative localisation was performed only with ^{99m}TcS, which demonstrated a sensitivity of 100% in this study, allowing FP in all 11 patients, with intraoperative use of the gamma probe (radio-guided). Cure rate was reported to be 100%, with 14 adenomas removed from the total 11 patients (2 with multiple adenomas detected at pre-operative localisation and confirmed intra-operatively). The authors conclude ^{99m}TcS to be useful in this setting, and have resultantly shown FP to be feasible.	(46)
16	Afzal et al	Management of hyperparathyroidism: a five year surgical experience	2011	Pakistan (Developing/Lower -Middle Income Country)	Retrospective study	35	32 of the total patients had primary HPT, with preoperative localisation with combined ^{99m}TcS & US, yielding a reported 100% accuracy rate. No individual localisation rates were provided. FP without IOPTH was performed in 27 cases (84,4%) and BNE in 5 cases (15,6%). 100% cure rate was revealed for both techniques, demonstrating safety and feasibility of this technique, with the authors concluding accurate pre-operative localisation & safe surgery allows total cure for these patients.	(47)
17	Baloch et al	Surgical management of hyperparathyroidism	2007	Pakistan (Developing/Lower -Middle Income Country)	Observational Case Series	16	11 of the total 16 patients in this case series presented with primary HPT, with preoperative localisation rate by combined US and ^{99m}TcS accurate in 100% of cases, allowing FP, with intraoperative methylene blue, in this group. The remaining patients had secondary HPT with parathyroid hyperplasia and total parathyroidectomy via BNE with auto-transplantation was performed for these cases. These techniques both demonstrated a 100% cure rate, with the authors concluding both techniques to be satisfactory treatments for their respective parathyroid pathology (primary vs secondary).	(48)
18	Koyuncu et al	Minimally invasive surgery in primary hyperparathyroidism	2023	Turkey (Developing/Upper-Middle Income Country)	Retrospective Analysis	116	Preoperative localisation accuracy rate by US & ^{99m}TcS was 94%, and 95% respectively. FP with intraoperative frozen secton was performed in all 116 patients, with a cure rate of 94,2% and morbidity of 1,7%. The authors conclude the technique to be the preferred treatment of choice for single gland disease, demonstrating the safety and feasibility of this technique.	(49)

UNDP = United Nations Development Program / WB = World Bank / Ref = references / US = ultrasound / ^{99m}TcS = ^{99m}Tc Sestamibi / FP = focused parathyroidectomy / MIP = minimally invasive parathyroidectomy / BNE = bilateral neck exploration / IOPTH = intraoperative parathyroid hormone / HPT = hyperparathyroidism

Table 3: Cure Rates

	Number of Studies	Number of Patients	Cure Rate
Focused Parathyroidectomy	18	1202	96,6%
Without Intra-operative Adjuncts	11	555 (46,2%)	95,4%
Intra-operative Adjuncts	7	647 (53,8%)	97,8%
• **IOPTH**	3	342 (28,5%)	97,1%
• **Frozen Section**	2	283 (23,5%)	96,9%
• **Methylene Blue**	1	11 (0,9%)	100%
• **Gamma Probe**	1	11 (0,9%)	100%

Discussion

Whilst the operative management of primary HPT has undergone profound evolutionary changes resulting in FP being considered the new standard of care for cases of primary HPT with unequivocally localised single gland disease, as recommended by the American Association of Endocrine Surgeons (AAES) and the Fifth International Workshop on Primary Hyperparathyroidism, the concern for practitioners in developing low and middle-income countries is the relevance of the evolutionary changes and the applicability of its outcome, namely FP, considering the basis for it all emanates from developed high-income countries (50,51).

As demonstrated by *Hurst et al (2005)* and *Adhikari et al (2021)*, evidence-based medicine and the guidelines they produce from high-income countries most often cannot be adhered to in resource constrained low and middle-income countries (52,53). As such, this review was conducted to address the question of feasibility of FP in terms of accessibility to and accuracy of preoperative localisation and adequacy of cure rates with this technique, in developing countries.

The first prerequisite to enable performing FP is adequate preoperative localisation. From this review, it was revealed that preoperative localisation was available in all developing countries from the articles included, with the most common modality used being the ^{99m}Tc Sestamibi (used in all studies) followed by US (used in 16 of the 18 studies).

The overall accuracy of ^{99m}Tc Sestamibi and US for preoperative localisation in these developing countries were 85,7% and 75,7% respectively. The overall accuracy of combined US and ^{99m}Tc Sestamibi was 95,2%. These results are in keeping with preoperative localisation rates reported from high-income countries. *Cheung et al (2012)* in their meta-analysis revealed sensitivities for ^{99m}Tc Sestamibi and US of 78,9% and 76,1% respectively (54). Combined ^{99m}Tc Sestamibi/US use for preoperative localisation has been reported to have a sensitivity of 96%, in keeping with the sensitivity of preoperative localisation from the developing countries in this study (55).

In a single lower middle-income country, Nigeria, *Olatoke et al (2013)* demonstrated preoperative localisation to be possible, but not feasible, as each ^{99m}Tc Sestamibi test required a 250km journey to access a facility with the necessary equipment (42).

Intraoperative adjuncts were used in 7 of the total 18 studies: IOPTH was used in 3 studies; frozen section in 2 studies; methylene blue in 1 study and the gamma probe in 1 study. The cure rate for patients undergoing FP with IOPTH was 97,1%, with an overall cure of 97,8% for patients undergoing FP with intraoperative adjuncts. In the remaining 11 studies of FP without intraoperative adjuncts, the overall cure rate was 95,4%.

These figures from the developing countries included are in keeping with reported cure rates from high-income countries. *Quinn et al (2021)* in their meta-analysis compared cure rates of patients undergoing FP with vs without IOPTH (56). The authors reported cure rates of 98% for FP with IOPTH and 94,8% for FP without.

The lowest cure rate in this review was reported by *Zitouni et al (2021)* from the lower middle-income Algeria, who reported a cure rate of 83,3% with FP (39). The limitation with this study was the low sample size of only 18 patients who underwent FP, thus the 83,3% represents 15 of the 18 cured, with 3 patients having persistence. Additionally, individual preoperative localisation accuracy rates were relatively low in this study, with US accurate in 60,7% of cases and ^{99m}Tc Sestamibi accurate in 66,5% of cases.

With the 18 studies from developing countries included in this review, a total of 1202 patients underwent FP with an overall cure rate of 96,6%. This is in keeping with reported cure rates from high income countries. *Ishii et al (2018)* in their meta-analysis of 5282 patients, from 14 included studies having undergone FP, demonstrated an overall cure rate of 96,9% (57).

From this review it is evident that not only is preoperative localisation accessible and accurate in these developing countries, but FP is also successfully being performed within these regions. The 2 lower middle-income countries with difficulties were Nigeria and Algeria, demonstrating that perhaps the upper-middle income developing regions are currently better suited to adapting to this minimally invasive technique.

Conclusion

Preoperative localisation is available in developing countries, with adequate accuracy rates, in keeping with rates described in literature from high-income countries. FP is performed in developing countries with adequate cure rates in keeping with that of RCT's published from high-income countries. Although some developing countries lack availability of certain intraoperative adjuncts, this was not prohibitive and cure rates with or without these adjuncts were similar in these countries.

With the established availability & impressive accuracy rates of preoperative localisation and the demonstrated success rates of FP, it is evident this technique is safe and feasible in developing countries.

Limitations

There were only 7 developing countries included in this review, thus limiting the relevance of this review to other developing countries. A small number of studies did not report individual preoperative localisation rates or overall cure rates, thus distorting representation of the overall localisation & cure rates.

Informed consent

Not applicable

Ethics

This study was approved for ethics exemption by the UKZN Biomedical Research Ethics Committee (BREC). BREC Reference: BREC/00005172/2023

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Conflict of Interest

None

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Appendices

Appendix 1: The Final Study Protocol

Title: FEASIBILITY OF FOCUSED PARATHYROIDECTOMY FOR PRIMARY HYPERPARATHYROIDISM IN A DEVELOPING COUNTRY

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1. BACKGROUND AND RATIONALE

1.1 Introduction

The parathyroid glands (PG) are specialised endocrine structures located in the neck, posterior to the thyroid gland, within the pre-tracheal fascia. Their main function is to produce parathyroid hormone (PTH), which is critical for calcium homeostasis, and thus normal physiologic function. Ordinarily, 4 glands are present: 1 pair superiorly and 1 pair inferiorly. However, variability in number (2 – 6) and location (≈ 16% ectopia including: mediastinum, retro-oesophageal and even lateral neck sites) is well documented. [1]

Parathyroid disease most often presents in the form of hypersecretion of PTH – termed hyperparathyroidism, which is the third most common endocrine disorder, following diabetes mellitus and thyroid disease. [2] Considering PTH is responsible for maintaining eucalcaemia, any hypersecretion results in hypercalcaemia. Thus, the symptomatic presentation in these patients involve hypercalcaemic symptoms; so-called 'stones, bones, groans and psychic moans' – derived from kidney stones, osteoperotic bone pain, peptic ulcer disease with abdominal pain groans and impaired cognition with psychic moans.

Hyperparathyroidism (HPT) may be classified broadly into 3 categories:

- Primary
- Secondary
- Tertiary

Primary HPT results from a direct PTH over-production from the PG, most often as a result of a parathyroid adenoma: and less commonly as a result of multiple adenoma's, parathyroid hyperplasia, parathyroid carcinoma and Multiple Endocrine Neoplasia (MEN) 1 and 2A.

Secondary HPT occurs most commonly as a consequence of chronic kidney disease (CKD). Specifically, secondary HPT results from PG over stimulation, PTH hypersecretion and resultant PG hyperplasia, in response to hypocalcaemia of CKD.

Tertiary HPT represents a persistence and progression of disease from secondary HPT in the setting of hypocalcaemic induced chronic PG over-stimulation, to profound hyperplasia and autonomous PTH secretion, persisting incessantly, post renal transplant.

The management of primary HPT necessitates parathyroidectomy in symptomatic patients and asymptomatic patients in certain instances. There is controversy as to which approach viz, bilateral neck exploration (BNE) or focused parathyroidectomy (FP) is superior in terms of cost and complications.

Surgical intervention for secondary & tertiary HPT, when indicated, always involves BNE as the pathophysiology in these two entities entails diffuse hyperplasia, and thus all four glands need to be inspected and the approach is therefore not an area of debate.

1.2 Background

Parathyroidectomy by way of BNE was first described by Felix Mandl in 1925, and subsequently became the recommended gold standard for all HPT requiring surgical intervention, with a reported cure rate of 95%. [3],[4] The rationale at the time, was the knowledge of multi-gland disease coupled with the inability to identify specific diseased glands pre-operatively. Since then, the standard of care has undergone a myriad of evolutionary advancements.

Minimally Invasive Parathyroidectomy (MIP), also known as FP or 'targeted' parathyroidectomy soon came to the fore. FP involves identification of the specific diseased PG pre-operatively and when coupled with intra-operative assays, affords the benefit of providing the surgeon with a roadmap, allowing a simple localised miniature incision directly over the affected gland, with easier excision, and obviation of inspection of the remaining PG's.

Born from the realisation that primary HPT is often a consequence of a solitary parathyroid adenoma (involving a single gland) in 80% of cases, the first less invasive rung on the parathyroidectomy evolutionary ladder, promoted by Roth et al in 1975 & Tibblin et al in 1982 [5],[6],[7] began with and entailed a unilateral neck exploration, without any pre-operative localisation. The side chosen for exploration was determined by either an oesophagogram, vascular PTH sampling, palpation or guess. The technique involved removal of all parathyroid tissue from one side, with the use of an intra-operative saline float test & oil red O staining. Excellent cure rates were realised, unfortunately only 43 of 102 patients revealed parathyroid pathology on the initial unilateral exploration, with 45 of 102 requiring contra-lateral exploration, thus a solution for correctly identifying the side of the offending PG pathology prior to exploration was desperately needed. [8]

With the advent of the nuclear scan Technetium 99m (Tc^{99}) Sestamibi – also known as parathyroid MIBI (99m Tc-methoxy isobutyl isonitrile) in 1989 [9], pre-operative localization was realized. A radiotracer (Tc^{99}) was injected intravenously where it flowed briefly until it was rapidly taken up by and localized in hyperfunctioning parathyroid tissue. A planar (2D) image was then taken with a nuclear medicine gamma camera which revealed the site of the offending hyperfunctioning tissue. This allowed identification of parathyroid adenomas and their exact location such that a single 10-20mm incision could be placed directly over the identified adenoma site, under a local, regional or general anaesthetic. Consequently, the modern FP was conceived.

This was revolutionary for cases with solitary adenomas, that were accurately localised. However, the accuracy of pre-op localization came to the fore as cases of missed multi-gland disease (multiple adenomas & multi-gland hyperplasia) arose. To address this problem, pre-operative localization progressed to entail a combination of the MIBI with existing ultrasonography. This realized a 13% increase in yield, however sensitivities for multi-gland disease remained concerning. [10]

Fortuitously, chemiluminometrics entered the fray, in the form of a quick PTH assay (QPTH). The QPTH is an intra-operative serum test, sampled post excision of adenoma, with a mere turn-around time of 15-20 minutes. Results revealing a more than 50% decline, compared to pre-operative levels, serve as confirmation of successful adenoma removal, eliminating the possibility of a potentially missed second adenoma, additional PG hyperplasia or hyperfunctioning ectopia. And, in the face of failed adequate QPTH decrease, then only a BNE would be warranted to explore the remaining glands for additional unidentified pathology. The addition of the QPTH has reportedly improved cure rates significantly from 91.9% to 99.1%. [11]

In the decades following the advent of MIBI, pre-operative localisation would see drastic improvements in technology and resultant sensitivities. The MIBI scan itself advanced drastically with evolutions in:

- Timing sequence – resulting in dual phase imaging
- Additional radiotracer isotope – resulting in dual isotope usage
- Image acquisition – resulting in progress from the original planar (2D) images to 3D images, making use of single photon emission computed tomography (SPECT) technology

In addition to the advancements in MIBI, further newer pre-operative localization studies have been developed with exceptional sensitivities demonstrated. [12]

Localisation Study	Reported Sensitivity	Study
MIBI SPECT/CT	86%	Wong et al, 2015
4D CT (contrasted triple phase CT)	94%	Bahl et al, 2015
MRI	97.8%	Agiro et al, 2018
PET/MRI	96.2%	Huber et al, 2018
4D MRI	100%	Merchavy et al, 2016
^{18}F-Fluorocholine PET (^{18}F-FCH PET)	100%	Huber et al, 2018
^{18}F-FCH PET/4D CT	100%	Piccardo et al, 2019

An additional adjunct in the FP armamentarium, so-called minimally invasive radio-guided parathyroidectomy (MIRP), described by Murphy et al. (1999), details the injection of radioactive tracer Tc99 2-4 hours prior to surgery, coupled with the use of an intra-operative gamma probe. A prescribed reading of ≥ 20% background radioactivity (BRA) of a removed suspected adenoma serves as confirmatory, obviating the need for frozen section. [13] Additionally, less than 20% BRA in any remaining tissue, serves as confirmation of no remaining hyperfunction pathological tissue, thus additionally obviating the need for intra-operative QPTH. [13]

The benefits of FP over traditional BNE include equivalent rates of cure (95 – 98%) [4], with added benefits of; the ability to be performed under a local anaesthetic, outpatient recovery, shorter operative time, desirable cosmesis, reduced nerve injuries and elimination of permanent hypoparathyroidism. Thus, in the setting of positive pre-operative localization, FP has become the new standard of care.

1.3 Rationale

With the enormous benefits and de rigueur standing of FP, it would be tempting to neglect the additional costs involved in the obligatory pre-operative localization studies and intra-operative QPTH assays required. Thus, FP cost-effectiveness studies ensued, with initial conclusions weighing against the overall benefits of FP, with the economic burden of requisite investigations being unjustified. [3]

With improvements in technology and resource availability over time, the cost of previously elusive pre-operative localisation studies decreased, and the literature reflected this by subsequently revealing FP's to be cost effective comparative to BNE alone, balanced by the added cost of increased operative time and longer hospitalization associated with the latter. [14]

Importantly, however, the mounds of literature we are guided by emanates from the 'developed, high-income world', where resources are far more abundant, with remarkable strides made in healthcare resource allocation. Unfortunately, in a developing world (middle-income) setting, with marked disparity between the private and public healthcare sector, resources are drastically limited, often to the point of tailoring guideline recommendations to local resource availability. [15]

Therefore, despite the described cost-effectiveness of FP with requisite localization & QPTH in studies from developed world literature, a developing country, such as South Africa, may not be able to rationalise this cost. In addition to the cost, availability is a concern, which, when considered, would drastically affect the feasibility of this procedure, over a traditional BNE that requires no additional localization or intra-operative adjuncts.

2. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

2.1 Overall Aim:

The aim of this scoping review serves to ascertain the feasibility, in terms of cost and availability, of the mandatory pre-operative localization studies, and intra-operative QPTH, necessary to facilitate a successful FP, for primary HPT in a developing country, South Africa.

2.2 Primary Objectives:

1. To ascertain if focused parathyroidectomy is performed in South Africa
2. To ascertain if pre-operative localization with Sestamibi/SPECT is readily available
3. To ascertain if intra-operative quick-PTH assay is readily available
4. To assess the cost of Sestamibi and QPTH locally
5. To assess the cost of a BNE locally
6. To ascertain if there are any 'high volume' parathyroidectomy centers in South Africa
7. To assess the outcomes of FP vs BNE locally

2.3 Primary Hypothesis:

Despite resource constraints in South Africa, focused parathyroidectomy requiring pre-operative localization and intra-operative QPTH is feasible

3. METHODS [16-21]

3.1 Study design

The research design will be in the form of a scoping review, making use of primary, secondary and tertiary literature, drawing from both published peer-reviewed and grey literature, specifically from within the last 15 years. The framework guide laid out by Arksey & O'Malley, including modifications published by Levac et al, will be followed. The suggested stages to be traversed include (1) identifying the research question; (2) identifying the relevant studies; (3) study selection, with specified inclusion and exclusion criteria; (4) charting the data and lastly (5) collating, summarising and reporting the results.

3.2 Setting and study population

The identified setting for this study is literature from developing countries, where resource constraints, in the form of prohibitive cost and lack of availability, often result in modification of 'best-practice' western guidelines.

3.3 Subjects

3.3.1 Sampling technique

- Search Criteria

An extensive literature search will be conducted, using Boolean logic operators such as 'AND' & 'OR', with the following key terms: 'primary hyperparathyroidism', 'parathyroidectomy', 'surgery', 'nuclear medicine', 'neck', 'developing countries', 'cost' and 'South Africa'. The keywords to be used comply with Medical Subject Headings (MeSH) terms, adjoined with relevant subheadings & qualifiers, falling within the jurisdictions of the MeSH tree structures. To broaden the exposure to relevant articles, the following non-MeSH conforming keywords will be additionally employed: 'focused parathyroidectomy', 'feasibility', 'developing world', 'economic viability', 'Sestamibi' and 'quick PTH'. The search will only look for literature from within the last 15 years.

- Identification of Evidence Sources

The extensive search will be conducted utilizing the following library databases: Pubmed/MEDLINE, Google Scholar, World Cat, Academic Search Complete via EBSCO host, Open Dissertations via EBSCO host, SA ePublications via SABINET African journals, SACat via OCLC and ProQuest.

These prodigious evidence sources were identified through their phenomenal reputations as leaders in library database provision, enabling access to a large cohort of invaluable research papers. The inclusion of local library databases, which forms part of the identified respectable evidence sources, stand to improve exposure to publications emanating from developing countries, thereby improving yield in addressing the research question.

3.3.2 Selection criteria

- Inclusion criteria

The basis for which studies will be selected includes: (1) studies providing evidence on surgical management of primary hyperthyroidism; (2) studies providing evidence on pre-operative localization; (3) studies providing evidence on a developing world approach to parathyroidectomy; and (4) studies providing evidence on economic burden of either parathyroidectomy option. No restriction on language will be employed, allowing for greater acquaintance.

- Exclusion criteria

International studies on surgical approaches for Primary HPT not providing cost information.

Local studies not providing information on operative approach for Primary HPT.

3.4 Screening, enrolment and study procedures

Upon exploration of the literature, screening will be initiated firstly by means of confirming relevance based on review of each title of the studies retrieved. Thereafter, abstracts will be scanned, followed by introductions and statements of purpose. If the studies fulfill the purpose of this review, the full text will be engaged.

3.5 Measures

3.5.1 Explanatory variables

1. Availability of Sestamibi scans in developing countries
2. Availability of QPTH developing countries
3. Cost of Sestamibi and QPTH
4. Availability of requisite parathyroid surgery expertise in developing countries
5. Availability of high-volume parathyroid surgery 'centers of excellence' in developing countries

3.5.2 Outcome variables

1. Prevalence of focused parathyroidectomy in developing countries
2. Cost associated with the various parathyroidectomy options

3.6 Data management plan

3.6.1 Data collection

All studies identified on the aforementioned library databases will be tabulated via use of Microsoft Excel. Further individual lists with specifics pertaining to included and excluded studies will additionally be tabulated as separate sheets, on one comprehensive document.

3.6.2 Validity

The eligibility of the research question will be tested using the PCC framework – namely; 'population, concept and context' framework, as recommended by the Joanna Briggs Institue (JBI). The population is identified as primary hyperparathyroid patients warranting parathyroidectomy. The concept is identified as cost and availability accounting for feasibility of focused parathyroidectomy comparative to bilateral neck exploration. Finally, context is identified as the developing world setting, South Africa.

Population	Human subjects undergoing investigation and surgery for primary hyperparathyroidism
Concept	Feasibility of focused parathyroidectomy vs bilateral neck exploration
Context	Developing world setting (middle-income), South Africa

Furthermore, to ensure validity of the scoping review, the quality of studies included will be assessed by means of the 'JBI critical appraisal checklist for systematic reviews and research syntheses' tool. The utility of this tool lies in its ability to appraise a studies methodological quality, ensuring the possibility of bias in either its design, conduct or analysis, is identified. (Appendix 1)

3.6.3 Data entering, storage and validation

The database making use of Microsoft Excel will be directly created and curated by the PI. Ongoing quality assurance will be completed prior to data entry. After entry, data will be edited and cross-checked such that no omissions and/or errors occur. Additionally, the database will be scrutinized by the Supervisor ensuring complete accuracy. Data will be stored on the study PI's computer and will be backed up daily on the central server; access will be limited to the PI.

3.7 Statistical considerations, Sample size and power

Data analysis plan

- Descriptive Analysis:

Primarily, the PRISMA-Scr extension framework and checklist will be adhered to in traversing data analysis, with data reporting of eligible studies via the PRISMA flow diagram. (Appendix 2)

3.8 Ethical considerations

The protocol will be submitted to the Biomedical Research Ethics Committee of UKZN for approval prior to study initiation. No literature research will be conducted, collected or captured prior.

3.8.1 Informed consent

The scoping review will require no informed consent as there is no participation of individuals required for this study

3.8.2 Confidentiality

This study will pose no risk to patient confidentiality as private medical records are not within the scope of this review.

Data will be stored on the study PI's computer and will be backed up daily on the central server. Access to database records and data files will be restricted to the PI.

3.8.3 Conflict of interest

None declared

4. STUDY TIMELINE

This review will require extensive literature research throughout a planned 6 month period

5. STUDY LIMITATIONS

This study takes the form of a scoping review, and as such, is reliant solely on available and accessible literature.

6. FUTURE DIRECTIONS

The study findings will be able to inform surgeons locally of feasibility of the attractive focused parathyroidectomy based on objective costs and availability of the procedure requisites.

7. BUDGET

R500

Justification of budget

Coverage of data cost required to search the relevant library databases.

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1. **Protocol Appendices**

Protocol Appendix 1

JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

Reviewer ________________________________ Date ________________

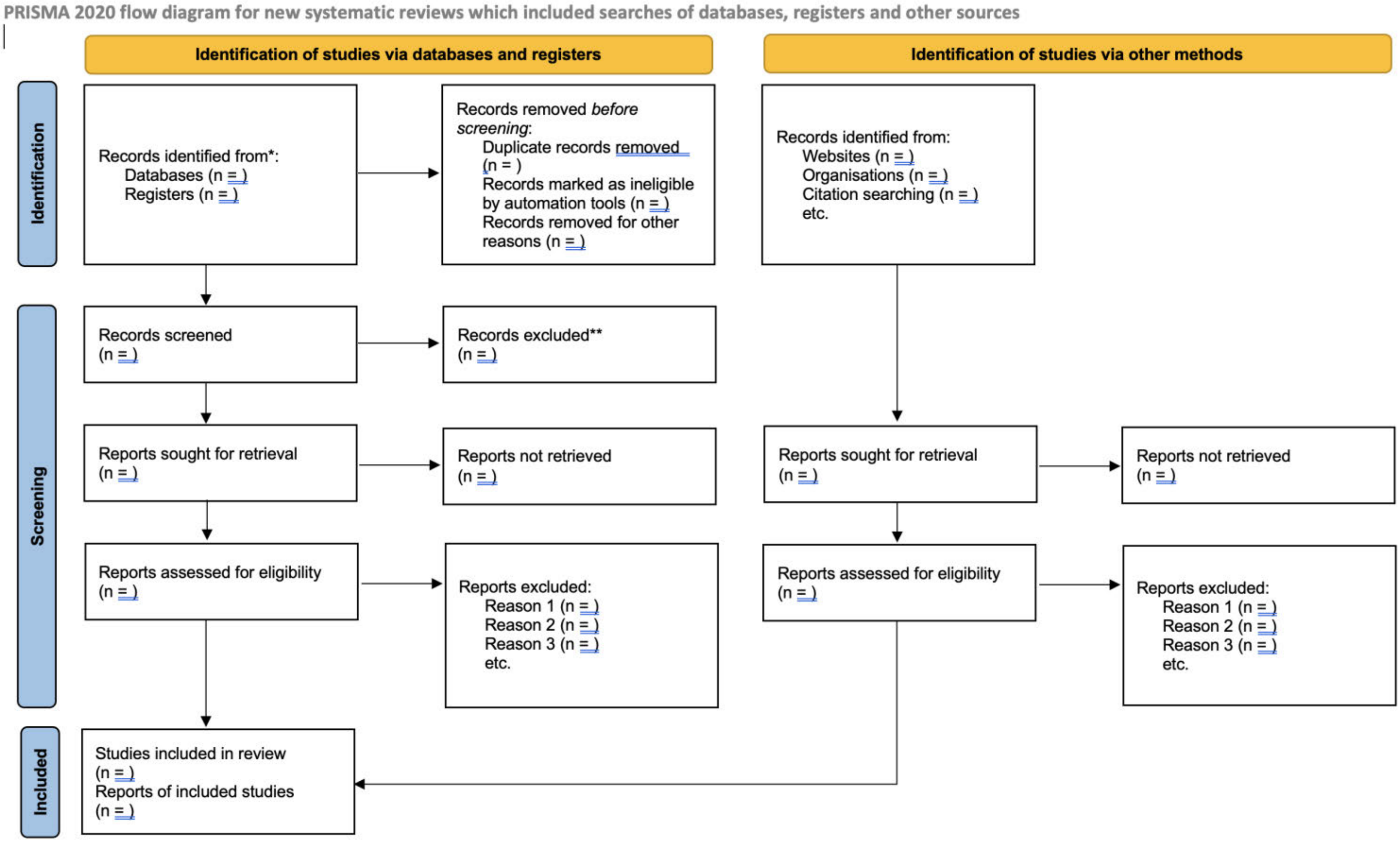
Author _________________________________ Year ________ Record Number

		Yes	No	Unclear	Not applicable
1.	Is the review question clearly and explicitly stated?	☐	☐	☐	☐
2.	Were the inclusion criteria appropriate for the review question?	☐	☐	☐	☐
3.	Was the search strategy appropriate?	☐	☐	☐	☐
4.	Were the sources and resources used to search for studies adequate?	☐	☐	☐	☐
5.	Were the criteria for appraising studies appropriate?	☐	☐	☐	☐
6.	Was critical appraisal conducted by two or more reviewers independently?	☐	☐	☐	☐
7.	Were there methods to minimize errors in data extraction?	☐	☐	☐	☐
8.	Were the methods used to combine studies appropriate?	☐	☐	☐	☐
9.	Was the likelihood of publication bias assessed?	☐	☐	☐	☐
10.	Were recommendations for policy and/or practice supported by the reported data?	☐	☐	☐	☐
11.	Were the specific directives for new research appropriate?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

____

Protocol Appendix 2



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Supervisor-Student Memorandum of Understanding

Prepared by Prof MJ Chimbari

This memorandum states the responsibilities of the supervisor(s) and postgraduate student and requires both parties to accept the responsibilities by signing.

Details of Student, Supervisors, and Project

Student Name: **.........Kapil Rugnath..**
Student Number: **.....207503757..**
School: **.....................College of Health Sciences - School of Medicine.................................**
Degree: **.....................MMED………...**
Supervisor(s): **...........Suman Mewa Kinoo...**
Research Topic: **.......Feasibility of Focused Parathyroidectomy for Primary.....................**
Hyperparathyroidism In A Developing Country................................
Date **..........................25 October 2022...**

Responsibilities of the Postgraduate Student

While there are many responsibilities carried by a student in pursuing postgraduate studies the following are the minimum expected.

1. Student should identify a research topic acceptable to the supervisor in order to register
2. Student must show commitment to the degree programme and undertake to produce a full proposal within 3 month of registering
3. Student must produce written work that is their best effort for comments by the supervisor
4. Student should meet at least once per month (in person or through skype) with the supervisor and have the courage to request for such meetings. In all such meetings the student should provide a brief report of their work and take minutes of the discussions and retain such records until the degree has been awarded
5. Students must keep a laboratory manual where all experimental procedures and data are recorded. This laboratory manual remains the property of the university
6. Student must demonstrate the highest level of scientific honesty at all *stages (proposal writing, seeking ethical approval, collecting data, analyzing data and writing thesis or manuscripts)* of the degree programme.
7. Students must familiarize themselves with the university's policy on Plagiarism
8. Students should follow the advice provided by the supervisor and if they choose not to they should
discuss the matter with the supervisor immediately
9. Student must always inform the supervisor of their whereabouts
10. Student should keep up to date with literature in their field of study and share any new literature
they come across with the supervisor
11. Student must agree to complete studies within the time specified in the CHS handbook for the specific degree programme
12. Student should allow the supervisor to publish their work if they do not do so or show interest one year after graduating on the understanding that the student will be co-author

Responsibilities of the Supervisor

1. Supervisor must support student at all stages of the degree programme *(settling down, proposal writing, ethical applications, data collection, data analysis and write up of thesis or manuscripts)*
2. Supervisor must be sensitive to the overall well-being of the student
3. Supervisor must have good knowledge of the research area of the student
4. Supervisor must be available to the student and should have regular meetings (face to face or by skype) with the student. If the supervisor must be away for an extended period they should identify a co-supervisor to assist the student during that period
5. Supervisor must read work submitted by student for comments and give feedback within 3 weeks depending on the nature of the work submitted
6. Supervisor must be constructively critical to the student's work
7. Supervisor must have sufficient interest in the work of the student
8. In instances of co-supervision the supervisors must avoid confusing the student by giving conflicting opinions/comments. If there are differences in opinion those should be discussed among the supervisors and the student given the agreed opinion.
9. Supervisor should, where funds pemlit, facilitate arrangements for masters and doctoral students to present a paper or a poster at an international conference as patt of training
10. Supervisor must provide an annual progress report on the reseai-ch and progression of the student to the discipline
11. Supervisor must protect the work of the student by not pre-maturely publishing it or assigning another student to similar work
12. Student must always be the first author of their work and any co-authorsllip with other people not on the supervision team should be clarified at an eat·ly stage of the project

Conflict Resolution

Should there be a conflict or disagreement between supervisor and student which cannot be resolved by the patties involved, then either patty can approach the Academic Leader Research or Dean and Head of School (or the College Dean of Research if the Dean and Head of School is one of the conflicting patties) about the conflict. The Dean and Head of School (or College Dean of Reseat·ch) will then either arbitrate or choose a senior academic of the School not involved in the conflict to arbitrate. The arbitrator's decision is final and cannot be appealed.

Signatures:

***Student*..........................** [redacted] ....

***Supervisor*.......................** I..

Co-Supervisor(s) ....

Academic ***Leader Research or D&HoS*..**

Zertifikat
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Certificat
Certificate

Promouvoir les plus hauts standards ethiques dans la protection des participants a la recherche biomedicale
Promoting the highest ethical standards in the protection of biomedical research participants

The University of Hong Kong

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Suman Mewa-Kinoo

a complete avec succes - has successfully completed

Introduction to Research Ethics

du programme de formation TRREE en evaluation ethique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2022/09/23
CID: 5z4plmTvq3

Professeur Dominique Sprumont
Coordinateur TRREE Coordinator

APPROVED BY SIWF FMH ISFM
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Conlinuing Education Programs (2-credits)

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Coordinateur TRREE Coordinator

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CID : JlQhHr.)Sd

Professeur Dominique Sprumont
Coordinateur TRREE Coordinator

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[REV : 20220217)

Appendix 2: The Guidelines for Authorship for the Journal selected for submission of the manuscript

South African Journal of Smge1y (SAJS)

Author Guidelines

Submitted manuscripts that are not in the correct format and without the required supporting documentation specified in these guidelines will be returned to the author(s) for correction and will delay publication.

AUTHORSHIP

Named authors must consent to publication by signing a covering letter which should be submitted as a supplementary file. Authorship should be based on substantial contribution to:

(i} conception. design. analysis and interpretation of data;

(ii) drafting or critical revision for important Intellectual content: and

(iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to ,-iww.ic.a)je,.o_rg and

(iv) exact contribution of each author must be stated.

DECLARATION OF CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a produa or subject that may constitute a conflict of interest. If **there is no conflict of interest to declare please include the following: The authors** declare no conflict of interest

FUNDING SOURCE

All sources of funding should be declared. Also define the Involvement of study sponsors in the study design, collectlon, analysis and interpretation of data; the writing of lhe manuscript the decision to submit the manuscript for publication. If **the study sponsors had no such involvement, this should be stated as follows: No funding source to be declared.**

RESEARCH ETHICS COMMITTEE APPROVAL

The submitting author must provide written confirmation of Research Ethics Committee approval for all studies including case reports. The ethics committee as well as the approval number should be Included. Please provide the Ethics Committee approval letter.

STATISTICAL ANALYSIS

Authors are advised to Involve medical statisticians at the protocol stage of their research project: to plan sample size. and the! seteaion of appropriate statistical tests for analysis and presentation.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying Information should not be published in written descriptions, photographs, and pedigrees unless the **information is essential for scientific purposes and the patient (or parent or guardian) gives Informed written consent for** publication. The patient should be shown the manusaipt *to* be published. Refer to lllCltlll(Jm,j g.

ETHNIC CLASSIFICATION

The rationale for analysis based on racio-ethnic-cultural categorisation should be indicated.

CATEGORIES OF SUBMISSIONS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Original articles

Original articles on research relevant to surgery should not exceed 3 000 words, no more than 30 references, with up to 6 tables or figures. A structured abstract under the following headings, Background, Methods, Results, and Conclusions is a requirement and should not exceed 250 words.

Scientific letters/short reports

Short reports should not exceed 1 500 words with a maximum of 10 references. Only one table or illustration is permissible. A structured abstract under the following headings, Background, Methods, Results, and Conclusions, is a requirement and should not exceed 250 words.

Case reports

Case reports should not exceed 1 500 words with no more than 10 references. Figures are limited to 2 figures and may include images or photographs. The case report should have three headings: Summary (not exceeding 100 words), Case report (with no introduction) and Discussion. Case reports will be published online only. The summary and the URL will appear in the printed version.

Video case reports (SAJS-VIDEO)

Video case reports should not exceed 1 500 words with 10 references and 6 figures. Heading should include Summary (not exceeding 100 words) and Case description (with three subheadings: Introduction, Case presentation and Discussion). The video file format must be only MP4 or MOV and should not exceed 300 MB and 8 minutes. Video case reports will be published online only. The summary and the URL will appear in the printed version.

How to do it

How to do it submissions should address a practical aspect of surgical or interventional (endoscopic or radiological) patient management in which a best practice technique or method to advance optimal patient management is presented in a standardised format. The submission should be structured with a short contextual introduction focussing on the indications for the procedure, followed by numbered sequential points that explain and illustrate the procedure and its complications. The total word count should not exceed 1500 words with a maximum of 10 references and 6 figures. Five keywords should be included.

Editorials

Opinions, etc. should not exceed 1 000 words and are welcome, but unless invited, will be subjected to the SAJS peer review process.

Review articles

Review articles relevant to surgery should not exceed 5 000 words, with a maximum of 50 references and no more than 6 tables or figures. A summary of 250 words or less is required.

Letters to the editor

Letters to the editor should be 400 words or less with only one image or table.

Obituaries

Obituaries should be 900 words or less and should be accompanied by a photograph.

MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

The manuscript should contain the title, abstract, keywords, article text and references.

The title page should be submitted as a supplementary file and should include:

- Qualification, affiliation and contact details of ALL the authors.
- Email addresses of all author must be provided.
- ORCID number of ALL authors must be provided – if authors do not have ORCID, please register at https://orcid.org/.
- Disclaimers: Acknowledgements, Declaration of conflict of interest, Funding declaration, Ethics declaration and ORCID.
- *A signed copy of the title page including the declarations must be provided in PDF format. An unsigned copy of the title page MUST be submitted in MSWord format.*

Abbreviations

All abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements

Scientific measurements must be expressed in SI units except blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age) should also be preceded by a space e.g. > 20 years. No spaces should precede ± and °, i.e. '35±6' and '19°C'.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...' Round **brackets** (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

General formatting

The manuscript must be in Microsoft Word. *Please DO NOT provide the manuscript in PDF format.* Text must be 1,5-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, except for Tables). *The manuscript must be free of track changes.*

ILLUSTRATIONS AND TABLES

If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

Tables may be embedded in the manuscript file **and** provided as **'supplementary files'**. They must be numbered in Arabic numerals (1,2,3...) and referred to consecutively in the text (e.g. 'Table 1'). Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged. Tables must be cell-based (i.e. not constructed with text boxes, tabs or enters) and accompanied by a concise title and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Figure 1)'. Figure legends: Figure 1: 'Title...'. All illustrations/figures/graphs must be of **high resolution/quality**: 300 dpi or more is preferable, but images must not be resized to increase resolution. Unformatted and uncompressed images must be attached as '**supplementary files**' upon submission (not embedded in the accompanying manuscript). TIFF and PNG formats are preferable; JPEG and PDF formats are accepted, but authors must be wary of image compression. Illustrations and graphs prepared in Microsoft PowerPoint or Excel must be accompanied by the original workbook.

REFERENCES

Authors must verify references from the original sources. *Only complete, correctly formatted reference lists will be accepted.* Reference lists may be generated with the use of reference manager software, but the final document must be delinked from the reference database or otherwise generated manually. Citations should be inserted in the text as superscript, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6] The superscript reference number should come after the punctuation mark.

All references should be listed at the end of the article in numerical order of appearance in the **Vancouver style** (not alphabetical order). Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus. Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al. First and last page, volume and issue numbers should be given. **Wherever possible, references must be accompanied by a digital object identifier (DOI) link and PubMed ID (PMID)/PubMed Central ID (PMCID).** Authors are encouraged to use the DOI lookup service offered by CrossRef. Crossref DOIs should always be displayed as a full URL link in the form https://doi.org/10.xxxx/xxxxx

Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. [http://dx.doi.org/10.1000/hgjr.182] [PMID: 2764753]

Book references: Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101. *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA jun, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.

Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).

Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: publisher name, year; pages. Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'. Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

COVERING LETTER

A covering letter to the editor is mandatory and must include statements that the manuscript has not been published previously and is not under review elsewhere. It should state details of any prior publication of the research in abstract form or in Congress proceedings. The letter must declare if any of the authors have a conflict of interest and that the requirements for submission, including ethics approval and patient permission for case reports have been fulfilled. All authors must sign the covering letter.

Please provide the names and email addresses of three possible reviewers for this manuscript.

REVIEW PROCESS

Manuscripts, after vetting by the editorial team, are assigned for peer-review to 3 reviewers, conversant with the particular field of research. The reviewers and the authors are blinded to each other's identity. The turn-around time for review and initial editorial decision notification aims to be within 6 weeks of submission.

PROOFS

A PDF proof of an article may be sent to the corresponding author before publication to resolve remaining queries. At that stage, **only** typographical changes are permitted; the corresponding author is required, having conferred with his/her co-authors, to reply within 2 working days in order for the article to be published in the issue for which it has been scheduled.

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Appendix 3: Ethical approvals

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

05 May 2023

Dr Kapil Rugnath (207503757)
School of Clinical Medicine
Medical School

Dear Dr Rugnath,

Protocol reference number: BREC/00005172/2023
Project title: Feasibility of focused parathyrofdectomy for primary hyperparathyroidism in a developing country
Degree: MMed

EXEMPTION LETTER

I refer to your application to BREC and wish to advise you that exemption from ethics review has been granted for this study.

This exemption will be **noted** at the next Biomedical Research Ethics Committee meeting to be held on **13 June 2023.**

Yours sincerely,

[redacted]

Prof D Wassenaar
Chair: Biomedical Research Ethics Committee

Appendix 4: Data collection tools

Scoping Review Data Collection Tool – Studies Included in Review								
	Author	Title	Year	Country & UNDP/WB Classification	Study Type	No. of Patients	Main Outcomes	Ref

Full Text Studies Excluded With Reasons								
	Author	Title	Year	Country & (UNDP/WB Classification)	Study Type	No. of Patients	Reason	Reference

Appendix 5: Raw data – Articles Encountered Upon Search of The Literature

1. Di Marco A, Mechera R, Glover A, Papachristos A, Clifton-Bligh R, Delbridge L, et al. Focused parathyroidectomy without intraoperative parathyroid hormone measurement in primary hyperparathyroidism: Still a valid approach? Surgery. 2021;170(5):1383-8.
2. Itani M, Middleton WD. Parathyroid Imaging. Radiologic Clinics of North America. 2020;58(6):1071-83.
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7. Vidal O, Saavedra-Perez D, Vilaça J, Pantoja JP, Delgado-Oliver E, Lopez-Boado MA, et al. Minimally-invasive Endocrine Neck Surgery. Cirugía Española (English Edition). 2019;97(6):305-13.
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10. Di Marco A, Mechera R, Glover A, Papachristos A, Clifton-Bligh R, Delbridge L, et al. Focused parathyroidectomy without intraoperative parathyroid hormone measurement in primary hyperparathyroidism: Still a valid approach? Surgery. 2021;170(5):1383-8.
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14. Kuzu F, Arpaci D, Cakmak GK, Emre AU, Elri T, Ilikhan SU, et al. Focused parathyroidectomy without intra-operative parathormone monitoring: The value of PTH assay in preoperative ultrasound guided fine needle aspiration washout. Annals of Medicine and Surgery. 2016;6:64-7.
15. Narayan R, Perkins RM, Berbano EP, Yuan CM, Neff RT, Sawyers ES, et al. Parathyroidectomy Versus Cinacalcet Hydrochloride–Based Medical Therapy in the Management of Hyperparathyroidism in ESRD: A Cost Utility Analysis. American Journal of Kidney Diseases. 2007;49(6):801-13.
16. Neves MCd, Abrahão AR, Abrahão M, Rosano M, Rocha LAd, Machado HKAG, et al. Sestamibi scan in renal parathyroidectomy: a worthwhile preoperative exam? Brazilian Journal of Otorhinolaryngology. 2022;88(5):740-4.
17. Ramonell KM, Fazendin J, Lovell K, Iyer P, Chen H, Lindeman B, et al. Outpatient parathyroidectomy in the pediatric population: An 18-year experience. Journal of Pediatric Surgery. 2022;57(3):410-3.
18. Werenski HE, Nguyen CJ, Johansson ED, Bunch PM, Randle RW. Value of Old Imaging for Patients Undergoing Parathyroidectomy for Primary Hyperparathyroidism. Journal of Surgical Research. 2023;282:147-54.
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Full Text Studies Excluded With Reasons								
	Author	**Title**	**Year**	**Country & (UNDP/WB Classification)**	**Study Type**	**No. of Patients**	**Reason**	**Reference**
1	Puthenveetil et al	Asymptomatic vs Symptomatic Primary Hyperparathyroidism: Comparison of Clinico-investigative Profile and Surgical Outcomes in Resource-Limited Setting	2022	India (Developing/Lower-Middle Income Country)	Multicentric retrospective study	213	No discussion on FP	(1)
2	Budge et al	Bone health in patients undergoing surgery for primary hyperparathyroidism at Tygerberg Hospital, Cape Town, South Africa	2020	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	56	No discussion on FP	(2)
3	Badii et al	Cost–benefit analysis of the intraoperative parathyroid hormone assay in primary hyperparathyroidism	2017	Italy (Developed/High Income Country)	Retrospective study	264	Study from a developed country	(3)
4	Zanocco et al	Cost-effectiveness of parathyroidectomy for primary hyperparathyroidism	2011	USA (Developed/High Income Country)	Literature Review	-	Literature from developed countries	(4)
5	Mihai et al	Cost-effectiveness of scan-directed parathyroidectomy	2008	UK (Developed/High Income Country)	Prospective Analysis	200	Study from a developed country	(5)
6	Baliski et al	The cost-effectiveness of three strategies for the surgical treatment of symptomatic primary hyperparathyroidism	2008	Canada (Developed/High Income Country)	Retrospective study	94	Study from a developed country	(6)
7	Flynn et al	Current status of surgical techniques for parathyroidectomy for untreated primary hyperparathyroidism: Is the technology worth it?	2010	USA (Developed/High Income Country)	Literature Review	-	Literature from developed countries	(7)
8	Karakas et al	Initial Surgery for Benign Primary Hyperparathyroidism: An Analysis of 1,300 Patients in a Teaching Hospital	2014	Germany (Developed/High Income Country)	Retrospective study	1300	Study from a developed country	(8)
9	Vaid et al	Minimally invasive parathyroidectomy: a community hospital experience	2011	USA (Developed/High Income Country)	Retrospective study	188	Study from a developed country	(9)
10	Elaraj et al.	Operative treatment of primary hyperparathyroidism: balancing cost-effectiveness with successful outcomes	2014	USA (Developed/High Income Country)	Literature Review	-	Literature from developed countries	(10)
11	Paravastu et al.	Parathyroidectomy in a district general hospital: Outcomes and evolution in the era of minimally invasive surgery	2012	UK (Developed/High Income Country)	Prospective Analysis	368	Study from a developed country	(11)
12	Piccin et al.	Pre-operative imaging workup for surgical intervention in primary hyperparathyroidism: A tertiary referral center experience	2021	Italy (Developed/High Income Country)	Retrospective study	336	Study from a developed country	(12)

13	Lubitz et al	Preoperative Localization Strategies for Primary Hyperparathyroidism: An Economic Analysis	2012	USA (Developed/High Income Country)	Literature Review	-	Literature from developed countries	(13)
14	Bhadada et al.	Primary hyperparathyroidism: insights from the Indian PHPT registry	2017	India (Developing/Lower-Middle Income Country)	Retrospective study	464	No discussion on FP	(14)
15	Dumzela et al	Profile of patients operated on for primary hyperparathyroidism at Chris Hani Baragwanath Academic Hospital	2020	South Africa (Developing/Upper-Middle Income Country)	Retrospective study	77	No discussion on FP	(15)
16	Jang et al	Racial disparities in the cost of surgical care for parathyroidectomy	2018	USA (Developed/High Income Country)	Retrospective study	899	Study from a developed country	(16)
17	Anderson et al	Rural General Surgery: A Review of the Current Situation and Realities from a Rural Community Practice in Central Nebraska	2012	USA (Developed/High Income Country)	Literature Review	-	Literature from developed countries	(17)
18	Frank et al	Surgery versus Imaging in Non-Localizing Primary Hyperparathyroidism: A Cost-Effectiveness Model	2020	USA (Developed/High Income Country)	Retrospective Cost Analysis	347	Study from a developed country	(18)
19	Pradeep et al.	Systematic Review of Primary Hyperparathyroidism in India: The Past, Present, and the Future Trends	2011	India (Developing/Lower-Middle Income Country)	Systematic Review	858	No discussion on FP	(19)
20	Aliabadi-Wahle et al	Treatment strategies for primary hyperparathyroidism: what is the cost?	2014	USA (Developed/High Income Country)	Retrospective Cost Analysis	740	Study from a developed country	(20)
21	Ahmed et al	Ultrasound - first imaging modality in the detection of parathyroid adenomas	2008	South Africa (Developing/Upper-Middle Income Country)	Prospective Analysis	12	No discussion on FP	(21)
22	Fatima et al	The Utility of Ultrasound in the Preoperative Localization of Primary Hyperparathyroidism: Insights from Pakistan	2020	Pakistan (Developing/Lower-Middle Income Country)	Retrospective study	79	No discussion on FP	(22)
23	Morris et al	The Value of Intraoperative Parathyroid Hormone Monitoring in Localized Primary Hyperparathyroidism: A Cost Analysis	2010	USA (Developed/High Income Country)	Literature Review	4280	Literature from developed countries	(23)
24	Wang et al	Would scan, but which scan? A cost-utility analysis to optimize preoperative imaging for primary hyperparathyroidism	2011	USA (Developed/High Income Country)	Literature Review	-	Literature from developed countries	(24)

*FP = Focused Parathyroidectomy

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