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ENDOCRINE

Feasibility and impact of a one-stop thyroid clinic in a low- and middle-income country

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Background: The study was done to evaluate the feasibility, safety and outcomes of a one-stop thyroid clinic (OSTC) in a low- and middle-income country (LMIC) setting.
Methods: This was a prospective non-randomised case control study consisting of patients with thyroid nodules evaluated and managed at a tertiary referral centre in an LMIC between February 2019 and January 2020. Patients were divided into two groups based on the kind of preoperative evaluation protocol: OSTC group (n =118) – OSTC protocol, and control group (CG, n = 108) – routine protocol.
Results: Baseline clinical characteristics of the two groups including median age (p = 0.13) and gender distribution (p = 0.76) were comparable. The majority of patients in both groups belonged to a low-income group (46.6% vs 47.3%; p = 0.91), followed by a middle-income group (35.6% vs 30.5%; p = 0.41). The median number of outpatient department visits (1 vs 3 days; p = < 0.001), waiting time for neck ultrasonography (1 vs 3 days; p = < 0.0001), fine needle aspiration cytology (1 vs 2 days; p = < 0.0001), and out of pocket expenditure (INR 3 965 vs 6 624; p = < 0.001) was significantly less in the OSTC group compared to the CG. Patients in the OSTC group reported better satisfaction levels (p = < 0.0001). Accuracy of diagnosis did not differ between the two groups (p = 0.14).
Conclusion: OSTC practice is feasible, provides comparative clinical outcomes and seems cost effective in an LMIC. This protocol can be adopted as a routine practice in any health system.
Keywords: one-stop thyroid clinic, low- and middle-income country, thyroid

Introduction

Thyroid nodules are a common clinical problem, and differentiated thyroid cancer is becoming increasingly prevalent due to awareness and adoption of ultrasonography (USG).[1] In developed countries, patients are referred to a specialist thyroid surgeon by a primary care physician and/or endocrinologist after adequate evaluation and often with a diagnosis. But in many low- and middle-income countries (LMICs), the system of referral is not that robust and a substantial number of patients with a thyroid nodule are referred without the basic investigations. This absence of strong referral systems between primary, secondary and tertiary centres results in inefficiencies in the diagnostic workup, often requiring multiple clinic visits to evaluate the presenting symptom. For patients, this results in significant anxiety and expense due to loss of income from lost workdays as well as ancillary costs such as transportation.[2-4] This lack of efficiency also places an unnecessary burden on secondary and tertiary level hospitals where large numbers of patients with minor ailments attend outpatient departments (OPDs).[5]

The idea of one-stop clinics was first introduced in 1995 for symptomatic breast disease and found to be effective.[6] The concept of one-stop clinics in developed nations has been extensively evaluated.[2,7-9] For LMICs, adopting the most efficient and patient-centred approach available is imperative to deliver on the World Health Organization (WHO) goal of health for all. To date, the one-stop thyroid clinic (OSTC) concept has not been adopted in routine clinical practice in LMICs, as evidenced by the lack of reports from these countries. While an OSTC is an accessible technology which can have a significantly positive impact on health resource utilisation in LMICs, establishing an OSTC in LMIC settings can be more challenging due to financial and resource restraints.

This study assesses the feasibility of an OSTC in our clinical context to facilitate the translation of patient-centric care into clinical practice through a structured framework with the possibility of wider application, if found successful.

Aim

The aim of this study was to evaluate the feasibility, safety and specific outcomes of an OSTC in an LMIC setting.

The primary endpoint was the diagnostic accuracy of fine needle aspiration cytology (FNAC) and the time required to obtain it.

Secondary endpoints were the number of clinic visits, patient costs incurred and patient satisfaction.

All patients filled in a proforma for cost analysis and satisfaction after getting USG and FNAC done.

Methods

Study design and setting

This was a prospective, non-randomised study consisting of patients presenting with a thyroid nodule at our centre, a tertiary super speciality academic centre in a state capital of the most populous state in India, between February 2019 and January 2020. Our department assesses patients from the north and east of India with both endocrine and breast complaints. All new patients with a thyroid nodule who gave consent to participate in the study were included, while patients not giving consent and paediatric patients < 10 years of age were excluded. The days designated for the OSTC were Monday, Tuesday, and Thursday, while those designated for the CG were Wednesday, Friday, and Saturday. Patients were thus divided into two groups based on the kind of preoperative evaluation protocol/days of visit: OSTC group (n = 118) – patients underwent evaluation through OSTC protocol, and control group (CG, n = 108) – patients underwent evaluation as per routine protocol.

OSTC protocol

All care was provided at a single site in the endocrine surgery OPD, where all the necessary tools and skills were made available, including a USG machine, FNAC facility, and blood collection centre. A multidisciplinary team (MDT) was available on-site on days designated for the OSTC. Patients were evaluated by a dedicated team consisting of endocrine surgeons, medical endocrinologists, radiologists and pathologists. The staff recruited for the project consisted of one consultant and resident each from endocrine surgery, radiology and pathology. The medical endocrinology department runs OPD clinics daily adjacent to the endocrine surgery OPD and a consultant and resident were available for consultations as and when needed. One paramedic was present for drawing of blood for fT4 and thyroid-stimulating hormone (TSH) estimation. Patient recruitment was done between 9:00–11:30 am. After registration and clinical evaluation, blood sample collection for serum T4 and TSH estimation, neck USG and FNAC were performed between 11:00 am–1:00 pm.

Serum T4 and TSH were estimated by chemiluminescence assay. Three millilitres venous blood was drawn and after serum separation serum fT4 (normal reference range 12–22 pmol/L) and TSH (normal reference range 0.4–4 uIU/ml) estimation was done on a Roche© COBAS-6000 system using prescribed kits. Results were verified by an endocrinologist.

USG was performed by an experienced radiologist using high-frequency probes. USG reports were summarised as benign, probably benign, probably malignant and malignant, and not according to the thyroid imaging reporting and data system (TI-RADS) classification.

Depending on the USG finding, a guided or blind FNA was performed by a pathologist. Adequacy of FNA was assessed on-site by the consultant pathologist. The slides were air dried and stained with May Grunwald-Giemsa stain. The results were reported as per the Bethesda cytopathology reporting system.[10] Patients for whom FNAC results showed an inadequate smear underwent a repeat FNA, always USG-guided, on the same or the next day in case the designated time for OPD was over and the radiologist was not available. Patients then returned home and were informed of the results within the next 2 days over the telephone or WhatsApp messaging system. MDT decisions were taken by the evening and future care plans were provided to the patients as soon as feasible. If the thyroid nodule turned out to be benign and surgery was not indicated, a physical or tele follow-up visit was arranged, depending on patient preference. Where surgery was indicated, the next OPD appointment was set for counselling and pre-anaesthetic evaluation. There was no deviation from the standard of care regarding the further management of the patient (Figure 1).

Routine protocol

Within the routine protocol, patients had a standard blood sample taken for thyroid functions on the first OPD visit. A FNAC was performed if an ultrasound had already been performed. If not, patients received an appointment for the ultrasound and/or USG-guided FNAC about 2–5 days after the initial visit. A follow-up appointment was then given at the same clinic for results and further discussion (Figure 2).

Scales and standards

- FNAC results were reported as per Bethesda cyto-pathology reporting system[10]
- Diagnostic accuracy was assessed by comparing the FNAC report with the final histology report in patients who underwent surgery
- Satisfaction score according to patients' own perception was recorded on a scale of one to five, one being not satisfied at all and five highly satisfied (1 – highly unsatisfied, 2 – unsatisfied, 3 – not sure, 4 – satisfied, 5 – highly satisfied)
- Cost analysis: patients were classified into low-, middle- and high-income groups, if the annual income was < 600 000 INR, 600 000–1 800 000 INR and > 1800 000 respectively.[11] We assessed the cost-of-the-care pathway for each patient from the patient perspective and included the cost of transportation, food, stay and loss of working hours for both patient as well as the accompanying attendant. We did not include the hospital staff costs for patient reception, evaluation and coordination as it was fixed for both the groups.

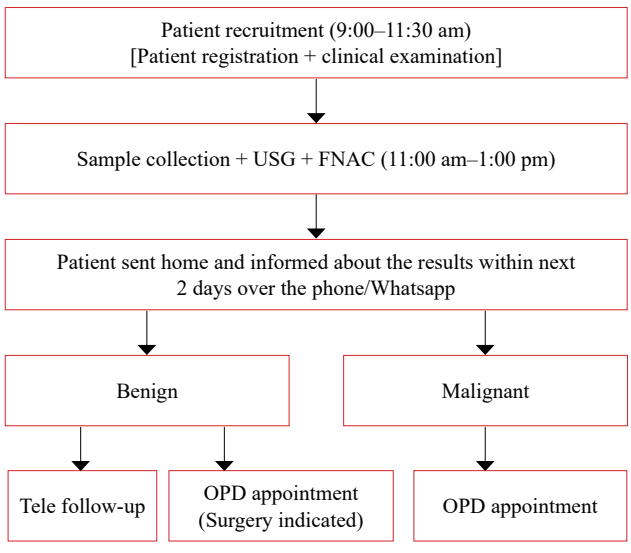

Figure 1

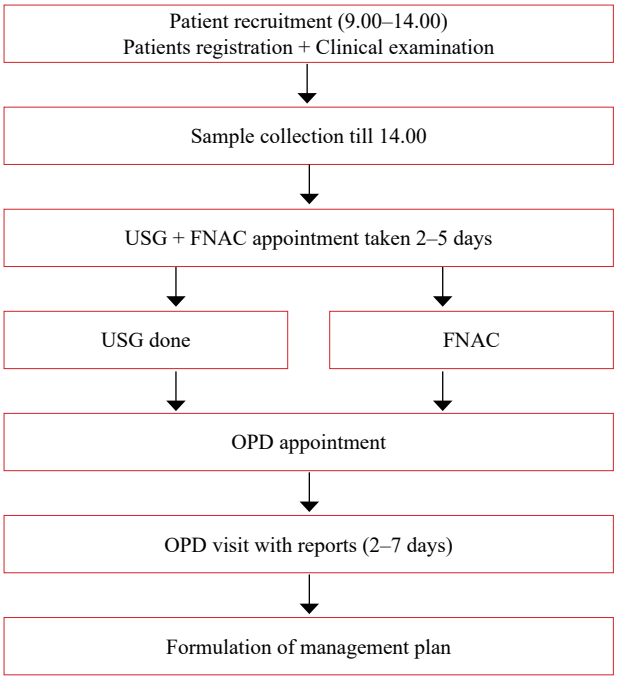

Figure 2: Routine protocol

Data collection and statistical analysis

Demographic details, pathology reports, biochemistry reports, ultrasound reports, surgery details, cost and satisfaction score data were entered in a pre-designed proforma and later into SPSS software. The statistical analysis was done using SPSS version 23. Continuous data was analysed using Mann–Whitey U test and frequency and proportion using chi-square test. A two-tailed $p < 0.05$ was considered significant for all tests.

Results

A total of 226 patients were allocated to two groups, 118 OSTC group and 108 CG, according to the day they presented. In the 118 OSTC cases, the OSTC protocol was successfully utilised in 62.7% patients ($n = 76$), while 42 patients (35.6%) required two visits and two patients (1.7%) required three visits. Of the 44 patients in the OSTC group who could not get evaluated the same day, 35 (79.5%) patients visited the hospital late and got registered after 12 pm so it was not possible to offer the full evaluation on the same day. These patients were asked to return the following day. The other nine (20.5%) patients could not undergo their USG/FNAC on the same day due to logistic issues. The most significant logistic issue was related to staffing: staff and/or doctors were posted exclusively to the OSTC for a fixed period of time (11:00 am–1:00 pm).

Baseline characteristics including median age (35 vs 40; $p = 0.13$) gender distribution (M:F – 1:4.3 vs 1:4.1; $p = 0.76$) and economic status (low – 46.6% vs 47.3%; $p = 0.91$; middle – 35.6% vs 30.5%; $p = 0.41$; high – 17.8% vs 22.2%; $p = 0.32$) were comparable between the two groups. The majority of patients in both groups belonged to a low-income group (46.6% vs 47.3%; $p = 0.91$) and the least to a high-income group as per the Government of India Ministry of Housing and Urban Poverty Alleviation. Most patients (63.4% vs 60%; $p = 0.64$) resided outside district and 19.6% vs 21.2% ($p = 0.79$) were from out of state. These figures did not differ significantly between the two groups. Table I summarises the basal characteristics of both the groups.

Number of OPD visits for obtaining USG ($p = < 0.0001$) and FNAC reports ($p = < 0.0001$) were significantly less in the OSTC group than the CG and so were the number of visits prior to obtaining diagnosis ($p = < 0.0001$). In the OSTC group, 62.2% patients could obtain a diagnosis after one OPD visit whereas the comparable figure in the CG

Table I: Comparative analysis of the two groups

S. No.	Characteristics	OSTC group $n = 118$	Control group $n = 108$	p-value
1.	Age in years: median (IQR)	35 (13–79)	40 (11–70)	0.13
2.	M:F	1:4.3	1:4.1	0.76
3.	Socioeconomic status			
	• low	55 (46.6%)	51 (47.3%)	0.609
	• middle	42 (35.6%)	33 (30.5%)	
	• high	21 (17.8%)	24 (22.2%)	
4.	Location			
	• outside district	75 (63.4%)	65 (60.2%)	0.872
	• outside state	23 (19.6%)	23 (21.3%)	
	• within district	20 (17.0%)	20 (18.5%)	
5.	Waiting period in days: median (IQR)			
	• For TSH report	1	1	0.82
	• USG	1 (1–3)	3 (1–5)	< 0.0001
	• FNAC	1 (1–2)	2 (1–4)	< 0.0001
6.	Number of visits prior to diagnosis: *n* (%)			
	• One	74 (62.7%)	8 (7.4%)	< 0.0001
	• Two	42 (35.6%)	13 (12.1%)	
	• Three	2 (1.7%)	87 (80.5%)	
7.	Interval between first visit attendance and diagnosis in days: median (IQR)	1 (1–3)	3 (2–5)	< 0.0001
8.	Satisfaction score: median (IQR)	5 (3–5)	4 (2–5)	< 0.0001
9.	Mean expenditure: SD (INR)	3 965 ± 1 548.82 (53 ± 20.7 *USD)*	6 624 ± 1 896 (88.5 ± 25.3*USD)*	< 0.0001

IQR – interquartile range, SD – standard deviation

Table II: FNAC results and comparison with histology

S. No.	Attribute	OSTC group *n* = 118	Control group *n* = 108	*p*-value
1.	**FNAC category: *n* (%)**			
	• I	1 (0.9)	0 (0.0)	0.306
	• II	92 (78.0)	95 (88)	
	• III	11 (9.3)	3 (2.7)	
	• IV	5 (4.2)	4 (3.7)	
	• V	1 (0.9)	1 (0.9)	
	• VI	8 (6.7)	5 (4.7)	
2.	**Final diagnosis: *n* (%)**			1.000
	• benign	57 (83.8)	44 (83.0)	
	• malignant	11 (16.2)	9 (17.0)	
3.	**False positive: *n* (%)**	2 (1.7)	0	0.498
4.	**False negative: *n* (%)**	1 (0.8)	2 (1.9)	0.607
5.	**Overall accuracy: *n* (%)**	97.5%	98.1%	0.14

was 7.4% ($p = < 0.0001$). Out-of-pocket mean expenditure incurred by each patient was significantly less in the OSTC group as compared to the CG (3 965 vs 6 624 INR or 55 vs 88.5 USD, $p < 0.0001$). The major expenditure was towards travel expenses and 48.5%, 33.3% and 18.2% of total expenditure incurred was on travel, food and lodging, respectively. When satisfaction level was analysed between the two groups, patients in the OSTC reported better satisfaction scores than the CG ($p = < 0.0001$). The distribution of score was 00 vs 2.8%, 0.8% vs 35.2%, 38.2% vs 50%, 61% vs 12% for a scale of 2–5 in OSTC versus the CG, respectively. No patient reported a satisfaction score of 1 or highly unsatisfied (Table I).

The majority of patients had benign USG findings (73% OSTC vs 79.6% CG), and most patients were euthyroid (96.6% OSTC vs 97.2% CG). There was no significant difference in the mean TSH levels in both groups (3.5 ± 2.9 mIU/L OSTC vs 4.2 ± 3.0 mIU/L CG; $p = 0.07$).

Sixty-eight patients (57.6%) in the OSTC group and 53 patients (49.1%) in the CG underwent surgery, while the remaining patients were followed up ($p = 0.22$). There was no statistically significant difference in the Bethesda category of OSTC and CG patients who had surgery (Bethesda II: 81% vs 81%, Bethesda III: 0% vs 2%, Bethesda IV: 3% vs 0%, and Bethesda VI: 16% vs 17%; $p = 0.67$). The final histology report was consistent with malignancy in 16.5% of patients undergoing surgery and did not differ significantly between the groups ($p = 0.69$). When correlated with final histology, two patients in the OSTC group had a false positive FNAC result and one patient a false negative FNAC result. Only two patients in the CG had a false negative FNAC result. ($p = 0.607$) Table II.

Discussion

The current study shows that an OSTC practice is feasible, helps in reducing diagnostic delays and results in comparative clinical outcomes as that of conventional consultations. Furthermore, the concept appears cost effective in an LMIC. This protocol can be adopted as a routine practice in any health system.

The majority of patients attending the OSTC required one visit for obtaining the diagnosis, while patients in our routine setting have to make, on average, three visits for the same. This difference was due to the fact that we performed USG as well as FNAC during the first visit to OSTC patients, whereas patients of the regular clinic had to wait an average of one to seven days for the appointment for USG and FNAC. Late-comers in the OSTC group had to make more than one visit to the hospital. It was rare that FNAC and USG could not to be performed on the same day.

To the best of our knowledge, this is the first study to assess the feasibility of an OSTC in a public hospital in an LMIC. We have come across two such studies with OSTC experience in New Zealand and the United Kingdom (UK). The results are similar to the current study in terms of reducing the number of patient visits and providing more efficient care.[2,9] In the study by Patel et al., the emphasis was on surgeon-performed USG and FNAC in the OSTC ($n = 119$) and the authors concluded that this strategy reduced the number of patient visits and resulted in the provision of more efficient care.[2] The UK study was aimed at decreasing the time from urgent referral to definitive treatment of patients with malignancy but only 11 patients with thyroid nodules were recruited in this study. A few other studies have concluded that surgeon-performed USG-guided FNAC of thyroid nodules is cost effective, decreases the number of visits and shortens the time to diagnosis as it is generally performed on the same day as that of the patient's visit.[12,13] Though in our case, the USG and FNAC were performed by the radiologist, the results were comparable to the previously published studies.

There are some concerns that breaking the news of malignancy in one-stop clinics could have a negative impact on patients' psychology. This issue has not been specifically addressed with regards to thyroid nodule evaluation, but studies conducted to evaluate such impact in cases of breast masses have concluded that same-day diagnosis appeared to reduce psychological distress for the 90% of clinic attendees diagnosed with a benign lump but may have a detrimental effect on women diagnosed with cancer.[7,8] A similar finding could also be true in the case of thyroid nodules, where the low incidence of thyroid cancer could mean an even larger percentage of patients who are successfully reassured at the first visit. In the current study, the satisfaction score was significantly better in OSTC. However, the satisfaction survey was completed prior to communicating the final diagnosis to patients. It is conceivable that the method of communicating the final diagnosis, particularly in the case of a malignant diagnosis, could have affected the final satisfaction score.

Diagnostic accuracy (i.e., correlation with preoperative FNAC and final specimen histology) amongst the operated

patients was 97.5% in the OSTC group and 98.1% in the control group (p = 0.14). This allays the fear regarding missing adverse diagnosis or misdiagnosis at the OSTC. The out-of-pocket expenditure in the control group was approximately 1.6 times more than in the OSTC group (difference of more than 35 USD). This is a significant saving for a population whose per capita income is just 2 104 USD.[14]

The doctor-to-patient ratio in LMICs falls short of WHO prescribed norms of 1:1 000. The total population of our country is 1.36 billion, and the doctor-to-patient ratio is 1:1 456.[15,16] This scarcity is even more pronounced when assessing the number of specialists available in overcrowded public tertiary care hospitals. Multiple visits to such hospitals by patients, a large proportion of whom pay out of pocket, is not a desirable situation. Establishing one-stop clinics could help in decreasing the burden on both hospitals and patients. The OSTC facilitates speedy diagnosis and a management strategy. These result in higher patient satisfaction and compliance. The evaluation of a thyroid nodule consists of three basic components: clinical evaluation followed by USG and FNAC. Provision of all these facilities during one visit, coupled with trained healthcare providers is the basic requirement for establishing an OSTC. Surgeons and physicians trained to perform USG and FNAC themselves could further improve the efficiency of OSTC.

The strength of the current study is that it is the first such prospective study from an LMIC. The weakness is that it is not randomised and patients were divided based on the day they visited the hospital. There are a number of caveats which concern the establishment and success of OSTC, the most important being staffing. The staffing was agreed upon for this specific project and consisted of some motivated individuals. Replicating the same in routine practice may not be very easy. Nonetheless, it proves that with a little adjustment, a more efficient healthcare delivery system can be created.

Conclusion

OSTC practice is feasible, provides comparative clinical outcomes to routine practice and is cost effective in an LMIC. This protocol can be adopted as a routine practice in any health system with ultrasound and FNAC facilities and ultimately could help reduce the clinical load on both the health services and patients. Training surgeons in the vagaries of thyroid USG (assessment and biopsy of nodules) would further facilitate OSTCs as it would result in less dependency on radiologists for this purpose. OSTCs could initially be introduced weekly with a limited number of patients. The service can be expanded once capacity to cater for more patients is developed.

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Conflict of interest

The authors declare no conflict of interest.

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Ethical approval

The study was approved by Sanjay Ghandi Institute of Medical Sciences Ethics Committee (IEC Code: 2018-184-MCh-EXP-4).

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