Development and pilot testing of a conversation aid to support the evaluation of patients with thyroid nodules

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Summary

Objective.—To support patient centered care and the collaboration of patients and clinicians, we developed and pilot tested a conversation aid for patients with thyroid nodules.

Methods.—We developed a web-based Thyroid NOdule Conversation aid (TNOC) following a human-centered design. A proof of concept observational pre–post study was conducted [TNOC vs. usual care (UC)] to assess the impact of TNOC on the quality of conversations. Data sources included recordings of clinical visits, post encounter surveys, and review of electronic health records. Summary statistics and group comparisons are reported.

Results.—Sixty five patients were analyzed (32 in the UC and 33 in the TNOC cohort). Most patients were women (89%) with a median age of 57 years and were incidentally found to have a thyroid nodule (62%). Most thyroid nodules were at low risk for thyroid cancer (71%) and the median size was 1.4 cm. At baseline, the groups were similar except for higher numeracy in the TNOC cohort. The use of TNOC was associated with increased involvement of patients in the decision making process, clinician satisfaction, and discussion of relevant topics for decision making. In addition, decreased decisional conflict and fewer thyroid biopsies as next management

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step was noted in the TNOC cohort. No differences in terms of knowledge transfer, length of consultation, thyroid cancer risk perception or concern for thyroid cancer diagnosis were found.

Conclusion.—In this pilot observational study, using TNOC in clinical practice was feasible and seemed to help the collaboration of patients and clinicians.

Keywords

thyroid nodules; thyroid cancer; shared decision making; conversation aids

Introduction

Caring for patients with thyroid nodules often includes deciding when to proceed with thyroid biopsy or monitoring with thyroid ultrasound (US). This decision is based on thyroid cancer risk, presence of symptoms associated with nodular enlargement, or hyperthyroidism secondary to toxic thyroid nodules.[1,2] Additionally, the decision of how to proceed depends on the patient's preferences, values, and context.[1,2] In fact, the American Thyroid Association (ATA) suggests consideration of patient factors that can affect the expected risks and benefits of a thyroid biopsy, such as high surgical risk or limited life expectancy.[2] Ideally, the end result of this process is a decision that makes sense to patients intellectually (i.e., I understand what I am doing), practically (i.e., I can do it), and emotionally (i.e., it feels right).[3]

Yet, in practice, these conversations are challenging. Clinicians often have difficulty communicating thyroid cancer risk, the risks/benefits of biopsy, and eliciting patients' preferences. As evidence of the complexity of these conversations, a survey of 196 patients that had just undergone a thyroid biopsy showed that patients had a limited understanding about the thyroid biopsy outcomes.[4] In fact, one third were not aware that their biopsy could be reported as non-diagnostic or indeterminate, and half did not know their risk of thyroid cancer. These results suggest a gap in the quality of decision making and the need to support conversations in clinical practice related to thyroid nodule diagnosis.[4]

Shared decision making (SDM) is a care approach that supports conversations between patients and clinicians about treatment or diagnostic decisions.[3] Tools that support SDM have been found to increase knowledge, accurate risk perceptions, satisfaction with the decision, and the number of patients achieving decisions that were informed and consistent with their values.[5] To support SDM between patients with thyroid nodules considering thyroid biopsy and their clinicians, we developed a Thyroid NOdule Conversation Aid (TNOC). Here, we report the development of TNOC and the results of the initial (pilot) evaluation of its impact on the quality of conversation and diagnostic decisions.

Material and Methods

Development and field testing of TNOC

We established a multidisciplinary team consisting of a senior design researcher, SDM experts, and clinicians with expertise in the care of patients with thyroid nodules to design a conversation aid prototype. The team followed a human-centered design approach that

involved: 1) review of the clinical evidence, 2) observation and analysis of usual practice, 3) development of an initial prototype, and 4) field testing in real encounters between patients and their clinicians with successive iteration of the prototype. The input from patients and clinicians was incorporated in this process. (Figure1) The development process continued until there was observable evidence that the conversation aid prototype supported the creation of a conversation consistently between patients and clinicians in which patients verbalized "trying on" the different options and testing the hypotheses that the option considered would be the best fit for them.[6–8] The evidence review focused on the evaluation of clinical practice guidelines recommendations, and clinical studies that guide the care patients with thyroid nodules receive.[2,9–11]

Preliminary (pilot) evaluation of TNOC's impact on quality of conversation and diagnostic decision

Study design, setting, and participants—We conducted a proof of concept pre-post observational study (non randomized) at the Endocrinology and Ear, Nose and Throat (ENT) outpatient clinics at the University of Florida between 2018–2019. Four endocrinologists and two ENT clinicians with expertise in the management of patients with thyroid nodules participated in the study. Eligible patients were   18 years and presented for the evaluation of a thyroid nodule. Pregnant patients, those with evidence of hyperthyroidism, or with available records of a previous biopsy of the nodule of interest were excluded. The study was approved by the University of Florida Institutional Review Board and informed consent was obtained at the time of enrollment.

We grouped participants into two temporal sequential cohorts, a methodology previously used by our group for the development and pilot testing of a conversation aid for patients with Graves' Disease.[12] The first cohort included patients presenting for the evaluation of a thyroid nodule and receiving counseling following usual care (UC). In other words, patients were evaluated and counseled as routinely done by the clinical team. This cohort allowed us to evaluate the usual practice for patients with thyroid nodules (information needed to develop TNOC) and was used as a comparison group. The second cohort included patients presenting for the evaluation of a thyroid nodule and receiving counseling that was supplemented by the use of TNOC. In other words, clinicians used TNOC to support their routine clinical discussion. TNOC was displayed and used during the clinical visit, as deemed fit by clinicians in their interaction with their patients. Patients who participated in the UC cohort were ineligible to participate in the TNOC cohort. (Figure 1)

Outcomes and data sources—Data sources for this study included clinical visit recordings, post visit surveys by patients, and baseline and post visit surveys by clinicians. See (Appendix 1) for a detailed description of measurements used.

<u>Recordings of clinical visits:</u> Video or audio recordings were assessed independently by two authors (NSO, DB) and disagreements were resolved by consensus to assess for: visit duration (minutes), fidelity of TNOC use (by scoring the presence of 10 elements included in the conversation aid and calculating a score of 1–100, with a higher number indicating higher fidelity of use), frequency of topics discussed related to the diagnosis of thyroid

nodules, proportion of encounters in which patients expressed a management preference, or either the patient or the clinician delegated the decision to the other party.

Furthermore, we evaluated the extent to which clinicians engaged patients in decision making using the OPTION score. This score, includes 12 items scored 0–4 and transformed into a 1–100 scale, with higher levels indicating higher patient involvement.[13,14]

In our practice, patients might first undergo an initial evaluation by a trainee focused on data gathering, followed by ultrasound assessment and counseling performed by an attending. Due to this dynamic process, it was feasible to only include the counseling section for some patients.

Patients post visit survey: Patients completed a post visit survey. This included demographic information, health status, literacy and numeracy (8 questions) [15–18], an assessment of knowledge related to thyroid nodules (12 statements to be evaluated as True/False/I don't know) and participant thyroid cancer risk perception (number from 0% to 100% or I don't know). We evaluated the percentage of patients that provided a risk estimate and whether this risk was correct. We followed the American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TIRADS) to estimate this risk, as the initial prototype allowed clinicians to enter their estimated thyroid cancer risk and/or follow the ATA framework.[1,9] Furthermore, patients rated their concern for a thyroid cancer diagnosis on a scale of 1–5 (not concerned to very concerned) and the degree of uncertainty about a particular course of action using the decisional conflict scale. This scale includes 16 statements, evaluated from 0–4, with higher numbers associated with higher degree of decisional conflict (reported as 0–100 scale).[19] Finally, we evaluated quality of communication and satisfaction with the encounter using Likert score scales. [20]

Clinicians baseline and post visit survey: Clinicians completed a baseline survey that included questions related to their clinical experience and demographics and a post visit survey after each clinical visit including questions related to their satisfaction (Likert score, with higher numbers indicating increased satisfaction) and decision making during the encounter.

Electronic health record: We used health records to obtain clinical characteristics related to the thyroid nodule, final management choice, and patients' demographics.

Statistical analysis and data management—Clinical, survey, and video-analysis data were uploaded into piloted electronic forms in RedCap.[21] Continuous variables were summarized as median and interquartile range (IQR). Categorical variables were summarized as frequencies and proportions. For demographic and baseline clinical characteristics, Wilcoxon rank sum test was used to compare continuous variables, and Chi-squared test or Fisher exact test to compare categorical variables.

As multiple participants may share one clinician, we calculated intraclass correlation (ICC) for each outcome. Wilcoxon rank sum test was used to compare continuous outcomes if its ICC was 0; univariable linear mixed model with random intercept was used if ICC was

non-zero. Chi-squared test or Fisher exact test was used to compare categorical outcomes if its ICC is 0; univariable generalized linear mixed model with random intercept was used if ICC was non-zero.

A multivariable generalized linear mixed model was fitted for outcome biopsy (received biopsy vs. not received biopsy) to evaluate the effect of group (TNOC vs UC), adjusting for nodule size and TIRADS (TR4/5 vs TR1–3). All statistical analyses were conducted using R 3.6.3.

Results

TNOC prototype development

The research team evaluated the clinical practice guidelines and associated clinical evidence guiding the care of patients with thyroid nodules, topics considered important by patients with thyroid nodules during the decision making process, and the clinical visit recordings of patients in the UC cohort, in an iterative process and with input from patients and clinicians to develop a conversation aid prototype. (Figure 1) This prototype included: 1) a description of the thyroid cancer risk displayed as a graph that allowed the clinician to enter the expected risk or follow the ATA US risk classification, 2) a discussion of the management options (e.g., US surveillance, thyroid biopsy, surgery), 3) a description of what each option means for the patient and potential risks for each option, and 4) an estimation of the cost related to each management option. In addition, clinicians were provided with a template to document the conversation in the electronic medical record. (Figure 2 and Appendix 2)

TNOC pilot testing

Participants demographics and clinical characteristics—Seventy-nine patients were enrolled in the study and 14 patients were excluded (e.g., technical issues related to recordings, previous biopsy, no identification of thyroid nodule on repeat US, no discussion about management options). The UC cohort included 32 patients and the TNOC cohort included 33 patients (Figure 1).

Most patients, were women (89.2%), middle aged (57 years), had completed graduate education (61.8%), and a minority had difficulty reading medical forms (10.9%) or inadequate health literacy (1.7%). There were no differences between groups, except for higher numeracy in the TNOC cohort (5.2 vs 4.6, p=0.027). There was a non statistically significant higher proportion of low risk nodules in TNOC (76% vs 66%, p= 0.532). Similarly, nodules in the TNOC cohort were smaller, although the difference was not statistically significant (1.2 cm vs 1.5 cm, p=0.279). Table 1 and Table 2 summarize other demographic and clinical characteristics between counseling groups.

Six clinicians participated in the study; most were women (83%), 67% were endocrinologists, and 33% were ENT. The median time in clinical practice after completing medical training was 3 years (IQR 1–10) with a median of 2 new patients with thyroid nodules evaluated weekly (IQR 2- 3).

Fidelity and decision making process—Most patients were evaluated only by an attending (senior clinician) (74%) and the complete clinical visit recording was available (77%).The duration of clinical visits was similar between groups (18 minutes TNOC cohort vs 15 minutes UC cohort, ICC= 0.16, p= 0.240) (Table3).

The fidelity of use of TNOC was high (90%, IQR 80%- 90%). The use of TNOC led to increased discussion of topics related to diagnostic management options and thyroid cancer risk. (Figure 3). The OPTION score was higher in the TNOC cohort compared to the UC cohort (33.3 vs 20.8, p<0.001) and more patients in the TNOC expressed a preference for a management option (45.5% vs 6.2%, p=0.002). Table 3 summarizes outcomes according to study group.

Knowledge, thyroid cancer risk estimate, level of concern, and conflict—There was no difference in knowledge transfer based on the percentage of correct answers between the two groups. More participants in the TNOC cohort compared to the UC cohort provided an estimate risk for thyroid cancer (65.6% vs 51.9%, p=0.42).

Furthermore, the TNOC cohort had a lower decisional conflict scale score (lower numbers indicate less conflict) compared to the UC cohort (2.3 vs 17.8, p=0.007). Similarly, patients in both groups felt their clinicians explained things in a way that was easy to understand (96.9% TNOC vs 85.2% UC, p=0.169) and felt their clinician showed respect (100% TNOC vs 92.6% UC, p=0.205) and listened carefully to them (100% TNOC vs 92.6% UC, p=0.205). Finally, clinicians in the TNOC cohort were more satisfied with their discussion and likely to recommend the way they worked together to others, when compared to those in the UC cohort. (Table 3)

Diagnostic pathway choice—Reviewed medical records showed more patients deciding for biopsy as the next step (15/32, 46.9%) in the UC cohort vs. **(5/33,** 15.2%) in TNOC cohort, p=0.021, ICC 0.44. In the UC cohort, out of the 15 patients that underwent thyroid biopsy 2 (13.3%) were in the ATA high risk category and 8 (53.3%) in the ACR-TIRADS 4–5 category. In the TNOC cohort, out of the 5 patients that underwent thyroid biopsy 1 (20%) was in the ATA high risk category and 4 (80%) in ACR-TIRADS 4–5 category. (Supplemental Table 1) Other management options included follow up US at different time intervals and deferring the decision (e.g., until review of previous medical records, discussion with other family members).

Multivariable model for thyroid biopsy—The odds of moving forward with thyroid biopsy as the next management step among patients in the UC group was 46.1 times higher of those in the TNOC group (OR 95% CI: 4.3–2057.9). Similarly, on average, for one cm increase of nodule size, there was 21.3 times higher odds of moving forward with a thyroid biopsy (OR 95% CI: 4.5 – 293.9). Finally, on average, the odds of receiving thyroid biopsy among patients with nodules TIRADS 4–5 was 18.4 times higher of those with nodules considered TIRADS 1–3 (OR 95% 3.0–269.8).

Discussion

We developed and field tested a conversation aid for patients with thyroid nodules (TNOC) following a human centered approach. In a pilot study evaluating a population consistent mostly of women presenting for the evaluation of incidentally discovered thyroid nodules (most low risk for thyroid cancer), the use TNOC during clinical practice was feasible and seemed to support the conversation of diagnostic strategies for patients with thyroid nodules. We found positive effects on the decisional conflict scale and OPTION score and higher levels of clinician satisfaction in the TNOC cohort when compared to the UC cohort. Moreover, the proportion of encounters in which important decision making topics were discussed was higher in the TNOC cohort. The proportion of patients who underwent biopsy as the next management step, was lower in the TNOC group. We found no statistical differences in terms of knowledge or accurate thyroid cancer risk assessment.

We are not aware of other conversation aids designed to support SDM in the initial evaluation of patients with thyroid nodules. In fact, although a large group of SDM tools have been developed to assist patients and clinicians in treatment decisions, fewer are available to help patients facing diagnostic decisions (outside of screening).[5,22–24] This is to some extent paradoxical, as conversations about diagnostic options are sometimes more challenging than treatment decisions, given diagnostic decisions usually involve a greater level of uncertainty and a larger decision tree (multiple hypothetical treatment options and prognosis based on different test results).[22] For patients with thyroid nodules, these challenges are evident given the need to consider variable risks for thyroid cancer, associated uncertainty, and the possibility of subsequent treatment decisions depending on the results of a biopsy or clinical changes during thyroid US surveillance. Moreover, "the stakes" associated with these clinical decisions are significant given that an incorrect/delayed diagnosis might lead to increased morbidity/unnecessary worry, but at the same time, excessive diagnostic interventions can have harmful consequences from overdiagnosis.[22,25,26]

We observed a low proportion of conversations including discussions about cost in the UC cohort, which was increased by the inclusion of cost as a variable for consideration in the TNOC prototype. Our previous survey found that 13% of participants considered cost as a very important variable when deciding between medical options. We included this variable in this initial TNOC prototype, given literature supporting cost as a variable of interest in medical decision making.[4,27,28] Field testing suggested limited value of cost when deciding between diagnostic options, as it rarely led to any significant conversation. The value of cost conversations emerges as another possible distinction between treatment and diagnostic decisions**.** However, is possible that contextual factors related healthcare coverage and access can affect the value of including cost in diagnostic conversations.[27]

The explicit discussion of management alternatives and clarifying the need to make a choice are important components of SDM.[29,30] Our results suggest that the use of TNOC increased the likelihood that management alternatives were explicitly discussed, in this case, thyroid biopsy and surveillance with US. We also found a lower proportion of participants in the TNOC cohort undergoing thyroid biopsy as the next step in management.

Diagnostic cascades of incidental findings have been associated with harm.[25,31] For many asymptomatic patients incidentally diagnosed with a thyroid nodule, the decision to perform a thyroid biopsy versus surveillance with US might represent an adequate reflection point to avoid further downstream consequences of this seemingly automatic diagnostic cascade.[1,32,33]

Similarly, the use of TNOC increased the proportion of encounters in which thyroid cancer risk was discussed, although we did not find a statistically significant effect on thyroid cancer risk perception. The TNOC prototype pilot tested in this study, allowed the clinician to directly entered an estimated thyroid cancer risk or to choose the risk according to the ATA classification. In addition, we used the ACR-TIRADS to determine if the thyroid cancer risk recalled by the patient was accurate or not (given it allows for classification of all nodules). The impact on accurate thyroid cancer risk recall by patients, might be affected by the risk stratification system used during the visit or as the gold standard and will require further evaluation. We have previously showed that most patients that had just undergone a thyroid biopsy were aware that evaluation for thyroid cancer was the main reason for thyroid biopsy. However, 56% were unaware of their risk for thyroid cancer.[4] Clinically, objective stratification of thyroid nodules according to their risk of thyroid cancer is extremely important. However, only a few studies have evaluated how patients undergoing evaluation for thyroid cancer use the risk for thyroid cancer when making management decisions. [2,9]

We found a non statistically significant difference in encounter duration, with longer duration of the visits where TNOC was used. Nonetheless, the overall visit time is likely within the allowed time for clinical consultations for patients with new thyroid nodules.[34,35]

The current study is limited by a single center observational design. In addition, it included a small number of clinicians, mostly endocrinologists and evaluated patients following a before and after design. Therefore, our evaluation of clinical outcomes can be affected by imbalances in clinical features and other unknown confounders and provides only preliminary information of the proximal effects of using TNOC when discussing diagnostic management options for patients with thyroid nodules. Similarly, TNOC was developed and pilot tested in an English speaking population with reasonable education and numeracy level. Further studies will need to evaluate the feasibility and acceptability of using TNOC to support the care of patients with thyroid nodules in other clinical settings, where linguistic and cultural adaptations might be required.[36] However, field testing of TNOC allowed for further refinement of the tool that now includes: 1) a pictogram in addition to a risk bar when displaying the risk for thyroid cancer, 2) the option for clinicians of using ACR-TIRADS for calculating a thyroid cancer risk, 3) simplified/staged decision tree, by including surgery as a secondary management option, 4) a printable summary for patients, and 5) increased attention to the prognosis/treatment of thyroid cancer. Additional field testing and evaluation on a pilot randomized clinical trial (NCT04472026; NCT04463719), will help further tailor TNOC to the needs of its users and assess the clinical impact, within the safeguards against bias of a randomized design.

Conclusion

Using TNOC during clinical visits was feasible and seemed to help patients with thyroid nodules and their clinicians collaborate when deciding the next diagnostic step and can serve as a reflection point for many patients that have incidentally entered the diagnostic cascade of thyroid nodules. The results of this feasibility and proof of concept study, supports the need for larger and randomized studies to increase our understanding of the effects of using TNOC in conversations with patients with thyroid nodules on the quality of diagnostic conversations and other proximal and distal patient important outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funding:

Availability of data and material:

Due to the nature of this research, participants of this study did not agree for their data to be shared publicly, so supporting data is not available.

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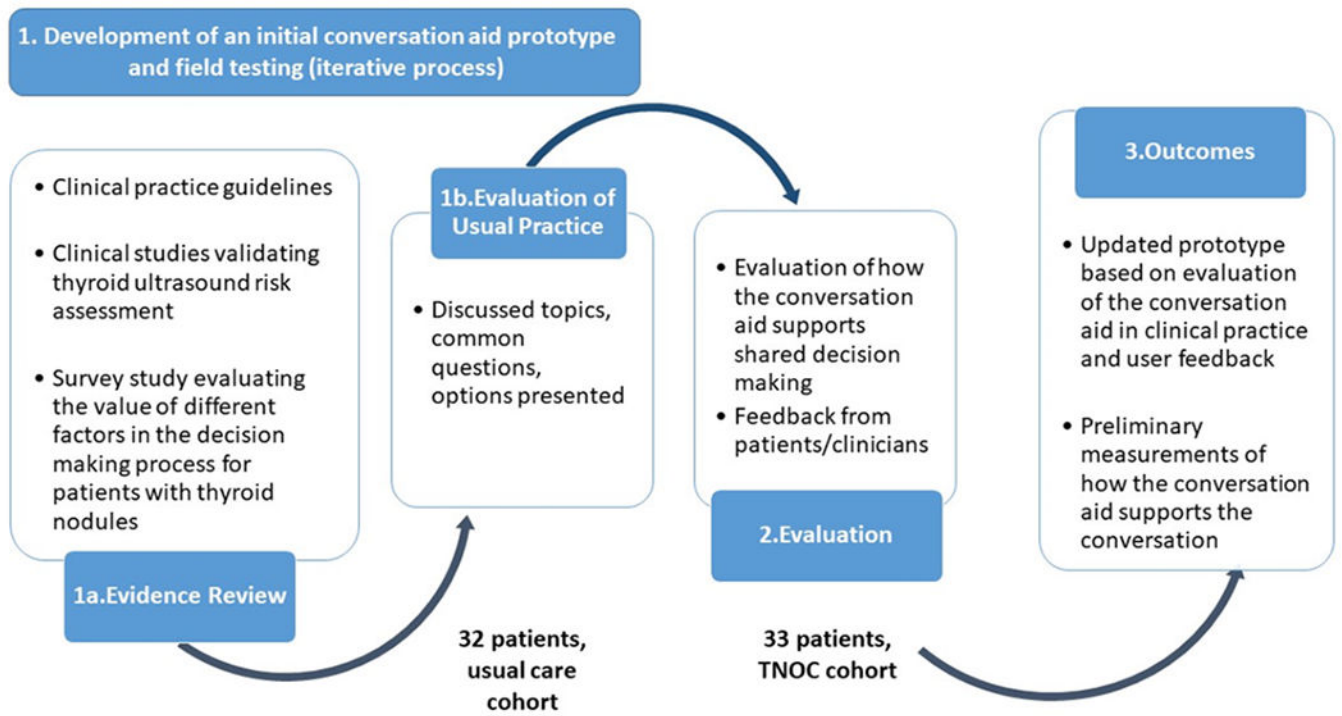
Figure 1.
TNOC development process and study design.
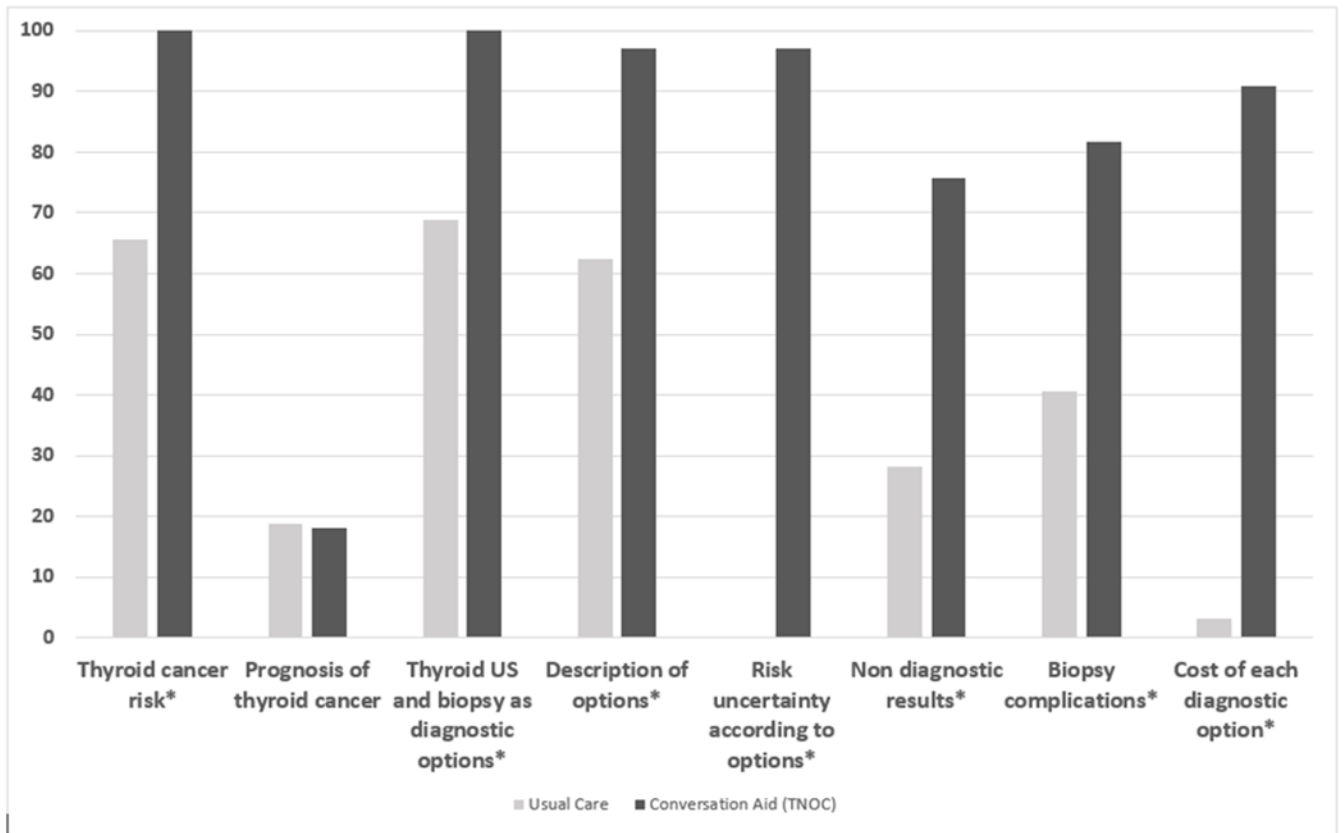TNOC, thyroid nodule conversation aid
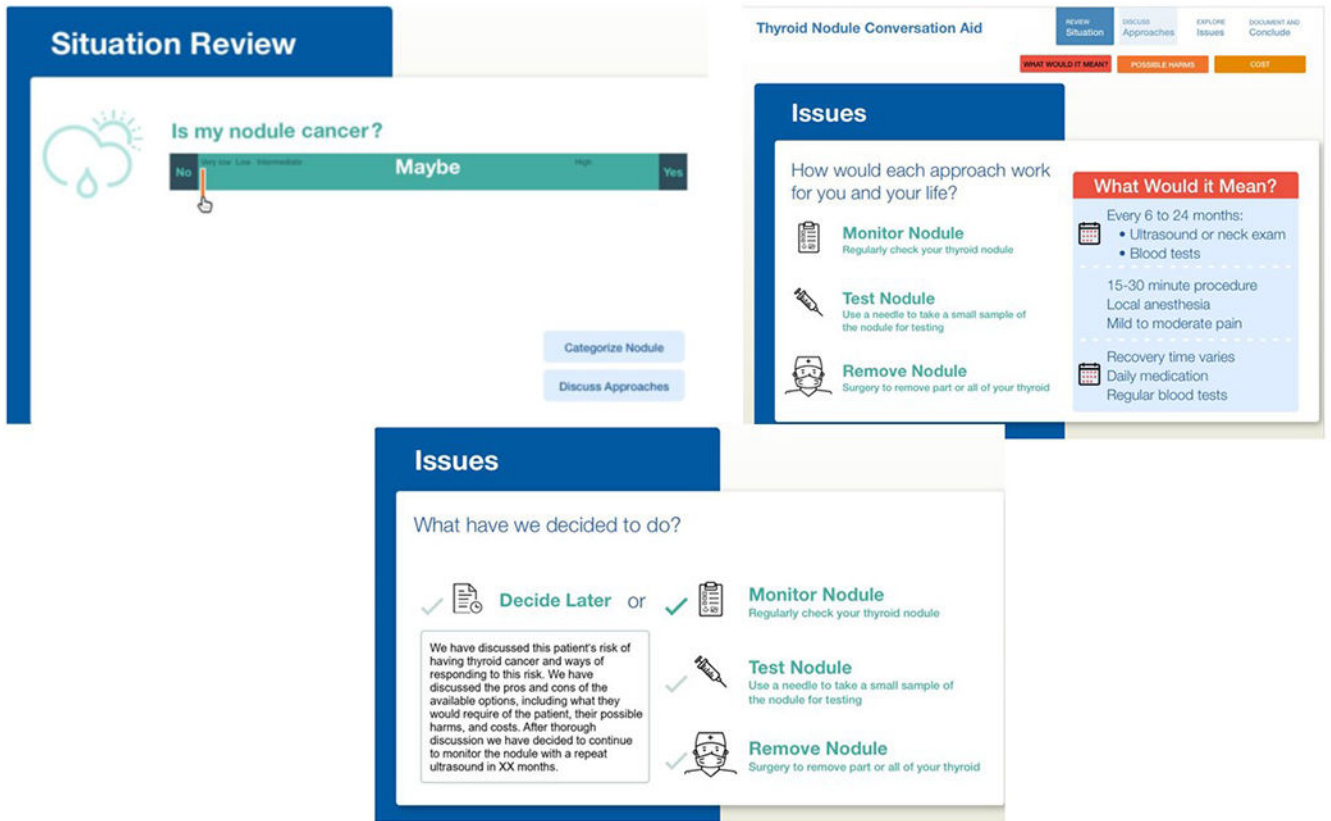
Figure 2, TNOC components
TNOC, thyroid nodule conversation aid

Figure 3.
Topics discussed according to counseling group. X axis, topics (%); Y axis, proportion of encounters. * Statistically significant difference

Table1.

Demographics according to counseling group

	UC cohort	TNOC cohort	All	*p*-value
Sex (women), n (%)	29 (90.6%)	29 (87.9%)	58 (89.2%)	1.000
Age (years), n, median (IQR)	3250 (39.2 – 68.2)	3359 (38 - 70)	6557 (38 - 69)	0.276
Marital status, n, (%)				0.855
Married	11 (44.0%)	16 (50.0%)	27 (47.4%)	
Hispanic/Latino/Spanish origin, n, (%)	6 (24.0%)	5 (15.6%)	11 (19.3%)	0.508
Race, n, (%)				1.000
White	21 (84.0%)	27 (84.4%)	48 (84.2%)	
Education, n, (%)				0.955
Graduate or professional degree	15 (65.2%)	19 (59.4%)	34 (61.9%)	
Some college, no degree	5 (21.7%)	9 (28.1%)	14 (25.5%)	
High school graduate	2 (8.7%)	3 (9.4%)	5 (9.1%)	
Less than high school	1 (4.3%)	1 (3.1%)	2 (3.6%)	
Household income, n, (%)				0.148
> $100,000	3 (13.0%)	11 (34.4%)	14 (25.5%)	
$40,000 -$100,000	10 (43.5%)	8 (25.0%)	18 (32.7%)	
Less than $40,000	10 (43.5%)	13 (40.6%)	23 (41.8%)	
Difficulty reading forms, n, (%)				0.686
Always, often, or sometimes	3 (13.0%)	3 (9.4%)	6 (10.9%)	
Rarely or never	20 (87.0%)	29 (90.6%)	49 (89.1%)	
Overall health, n, (%)				0.778
Excellent or very good	12 (44.4%)	16 (51.6%)	28 (48.3%)	
Good, fair, or poor	15 (55.6%)	15 (48.4%)	30 (51.7%)	
Daily medicines n, median, (IQR)	274 (1 - 7)	315 (0 - 7)	584.5 (0.2 - 7)	0.608
Confidence filling medical forms (health literacy) , n, (%)				1.000
Extremely, quite a bit, somewhat confident	26 (100%)	31 (96.9%)	57 (98.3%)	
A little bit confident	0	1 (3.1%)	1 (1.7%)	
Numeracy n, median, (IQR)	264.6 (3.8 - 5.5)	325.2 (4.7 - 6.0)	584.8 (4.2 - 5.8)	*0.027*

Abbreviations: UC, usual care; TNOC, thyroid nodule conversation aid; IQR, interquartile range

Number of missingness: Marital status, n=8; Hispanic/Latino/Spanish origin, n=8; Race, n=8; Education, n=10; Household income, n=10; Difficulty reading forms, n=10; Overall health, n=7; Daily medicines, n=7; Confidence filling medical forms (health literacy), n=7; Numeracy, n=7.

Table 2.

Clinical and recording characteristics according to counseling group

Clinical Features				
	UC cohort	TNOC cohort	All	*p*-value
Nodule discovery, n, (%)				**0.04**
Diagnostic work up	8 (25.0%)	1 (3.0%)	9 (13.8%)	
Incidental (exam)	5 (15.6%)	12 (36.4%)	17 (26.2%)	
Incidental (imaging)	13 (40.6%)	10 (30.3%)	23 (35.4%)	
Other	3 (9.4%)	6 (18.2%)	9 (13.8%)	
Patient's complaint	3 (9.4%)	3 (9.1%)	6 (9.2%)	
Screening	0	1 (3.0%)	1 (1.5%)	
History of radiation therapy to the neck, n, (%)	0	2 (6.1%)	2 (3.1%)	0.492
Family history of thyroid cancer, n, (%)	2 (6.2%)	4 (12.1%)	6 (9.2%)	0.672
History of Hypothyroidism, n, (%)	6 (18.8%)	4 (12.1%)	10 (15.4%)	0.511
MNG, n, (%)	26 (81.2%)	21 (63.6%)	47 (72.3%)	0.190
ATA US risk classification, n, (%)				0.391
High suspicion	2 (6.2%)	2 (6.1%)	4 (6.2%)	
Intermediate suspicion	7 (21.9%)	2 (6.1%)	9 (13.8%)	
Low suspicion	13 (40.6%)	12 (36.4%)	25 (38.5%)	
Very low suspicion	7 (21.9%)	12 (36.4%)	19 (29.2%)	
Benign	0	1 (3.0%)	1 (1.5%)	
No class	3 (9.4%)	4 (12.1%)	7 (10.8%)	
ACR-TIRADS, n, (%)				0.559
TR1	0	1 (3.0%)	1 (1.5%)	
TR2	7 (21.9%)	12 (36.4%)	19 (29.2%)	
TR3	14 (43.8%)	12 (36.4%)	26 (40.0%)	
TR4	9 (28.1%)	6 (18.2%)	15 (23.1%)	
TR5	2 (6.2%)	2 (6.1%)	4 (6.2%)	
Nodule Size (cm) median (IQR)	1.5 (1.3 – 1.8)	1.2 (1.0 - 2.0)	1.4 (1.1-1.9)	0.279
Clinical Recording Features				
Type of clinical visit recording (video or audio), n, (%)				
Video	3 (9.4%)	14 (42.4%)	17 (26.2%)	**0.006**
Number of clinicians that evaluated the patient (senior clinician only or trainee and clinician), n, (%)				
Trainee and clinician	8 (25.0%)	9 (27.3%)	17 (26.2%)	1.000
Type of clinical visit recording (complete visit history and counseling, or counseling only), n, (%)				
Complete History and counseling	28(87.5%)	22 (66.7%)	50 (76.9%)	0.089

Abbreviations: UC, usual care; TNOC, thyroid nodule conversation aid; MNG, multinodular goiter; ATA US, American Thyroid Association Ultrasound Risk classification; ACR TIRADS, American College of Radiology Thyroid Imaging Reporting and Data System; IQR, interquartile range. Number of missingness: Nodule Size, n=1.

Table3.

Outcomes according to counseling group (patient and clinician post visit survey)

	UC cohort	TNOC Cohort	ICC	*p*-value
Clinical Visit Recordings				
Fidelity of use (conversation aid), median (IQR)		90 (80 - 90)		
Patient expressed a preference for a management option, n, (%)	2 (6.2%)	15, (45.5%)	*0.03*	*0.002*
Patient delegated decision to the clinician, n, (%)	0	4 (12.1%)	0	0.114
Clinician delegated the decision to the patient	1 (3.1%)	0	0	0.492
OPTION Score, median (IQR)	20.8 (16.7 – 25.5)	33.3 (31.2 – 37.5)	*0.01*	*<0.001*
Duration clinical visit (minutes), median (IQR)	15 (11.5 - 21.2)	18 (11 - 25)	*0.16*	0.240
Patient Survey				
Knowledge all questions, median (IQR)	66.7 (52.1 – 81.2)	66.7 (50 – 77.1)	0	0.969
Knowledge 7 questions included in TNOC, median (IQR)	71.4 (57.1 – 82.1)	71.4 (57.1 – 85.7)	0	0.687
Knowledge 5 questions not in TNOC, median (IQR)	60 (60 - 80)	60 (60 - 80)	0	0.580
Provided a risk estimate for thyroid cancer, n, (%)	14 (51.9%)	21 (65.6%)	0	0.420
Correct risk estimate for thyroid cancer [*], n, (%)	12 (85.7%)	16 (76.2%)	0	0.676
Very Concerned for a diagnosis of Thyroid Cancer diagnosis, n, (%)	17 (65.4%)	21 (67.7%)	0	1.000
Decisional conflict scale, median (IQR)	17.8 (2.0 – 37.1)	2.3 (0 – 20.3)	*0.01*	*0.007*
Would you recommend the way you and your clinician shared information about your thyroid nodule to other patients?, median (IQR)	1 (1 - 1.5)	1 (1 - 1)	**0.79**	0.104
Clinicians Survey				
Satisfaction with the discussion you had with your patient?, median (IQR)	5 (5 - 6)	6 (5 - 6)	*0.36*	*0.003*
Likelihood of recommending the way you and your patient worked together to make a decision?, median (IQR)	7(6 – 7.2)	8(7 - 8)	*0.09*	*<0.001*

Abbreviations: UC, usual care; TNOC, thyroid nodule conversation aid; ICC, intraclass correlation coefficient; IQR, interquartile range.

[*] This is calculated among those 35 participants who provided risk estimate for thyroid cancer, therefore, the proportion denominator is 35 (14 for UC group and 21for TNOC group).

Number of missingness: Knowledge all questions, n=7; Knowledge 7 questions included in the CA, n=7; Knowledge 5 questions not included in the CA, n=7; Provided a risk estimate for thyroid cancer, n=6; Very Concerned for a diagnosis of Thyroid Cancer diagnosis, n=8; Decisional conflict scale, n=7; Would you recommend the way you and your clinician shared information about your thyroid nodule to other patients, n=7; Satisfaction with the discussion you had with your patient, n=4; Likelihood of recommending the way you and your patient worked together to make a decision, n=4.