Thyroid Research

RESEARCH Open Access

Improving fine needle aspiration in value-based thyroid cancer care: an interrupted time series analysis

Esmée K. J. van der Poort[1*], Nicky Stam-Thelosen[2], M. Elske van den Akker-van Marle[1], Lieke Welling[3], Marieke Snel[4], Menno J. P. Toirkens[2] and Wilbert B. van den Hout[1]

Abstract

Background Value-Based Health Care (VBHC) implementation motivates providers to reduce unnecessary procedures to improve outcomes and costs, i.e. value. In thyroid cancer care, adequate use of Fine Needle Aspiration (FNA) may prevent downstream diagnostics, costs, and delays in the care process. This study aims to evaluate the impact of needle selection in FNA on Bethesda I classifications, duration of FNA appointments, and care utilization.

Methods In October 2021, a Modified Menghini-type needle needle replaced the regular syringe needle used for FNA. An interrupted time series (ITS) analysis using generalized linear models was conducted with data from radiology and pathology reports coupled with care utilization data at the patient level. Outcomes included frequency of Bethesda I classifications per month, appointment time, and health care utilization in the first patient year (in 2024€).

Results Between July 2020 and May 2022, 345 FNA in 224 patients were included. Implementation of the Modified Menghini-type needle needle was associated with a 78% level decrease in the odds of Bethesda I classification during FNA (OR (95% CI) 0.22 (0.06;0.71)), and, on average, a 4% (1.25 min) reduction in FNA appointment time. Despite a higher FNA unit cost postintervention (additional cost of €17.56 per FNA), there were no changes in the diagnostic and overall costs.

Conclusion VBHC implementation provides the tools to identify and monitor improvement projects that enhance the value of thyroid nodule diagnostics and management. Implementing a Modified Menghini-type needle needle in FNA resulted in increased adequate diagnostic results, time savings, and no changes in diagnostic and care costs.

Clinical trial number Not applicable.

Keywords Fine needle aspiration, Thyroid, Needle selection, Value-based health care

*Correspondence:
Esmée K. J. van der Poort
e.k.j.van_der_poort@lumc.nl
[1]Department of Biomedical Data Sciences, Leiden University Medical Center, Leiden, the Netherlands
[2]Department of Radiology, Leiden University Medical Center, Leiden, the Netherlands
[3]Department of Surgery, Leiden University Medical Center, Leiden, the Netherlands
[4]Department of Internal Medicine, Leiden University Medical Center, Leiden, the Netherlands

Background

Value-Based Health Care (VBHC) is a care delivery model that aims to optimize the value of care to the patient [1, 2]. VBHC supports the organization of care around the patient in care pathways and the continuous improvement of value by measuring outcomes over costs [3]. Following the VBHC principles, providers are incentivized to offer patient-centered care that reduces unnecessary procedures and improves patient-relevant outcomes. In thyroid cancer care, optimizing diagnostics is an important focal point of VBHC implementation [4]. Adequate use of, for example, fine needle aspiration (FNA) may prevent inadequate use of downstream diagnostics, higher downstream costs, and delays in the care process [5].

FNA is an essential diagnostic tool to determine the cancerous nature of thyroid nodules without surgical intervention [6]. Overall, 50% of adults develop a nonpalpable thyroid nodule during their lifetime, and 6–8% of adults develop a palpable thyroid nodule [7]. Currently, there is an increase in incidental discovered thyroid nodules due to increased diagnostic imaging [8]. A majority of thyroid nodules are benign, as only 5–10% of thyroid nodules are clinically diagnosed as cancer [7, 9]. FNA rightfully distinguishes between benign and malignant thyroid nodules around 70% of the time [10]. A downside to FNA is the possibility of a non-diagnostic outcome, for example when the sample obtained during the procedure provides insufficient cellular material. A non-diagnostic outcome is classified as Bethesda I in the 2017 Bethesda System for Reporting Thyroid Cytophathology [11].

The VBHC pathway for thyroid cancer at an academic teaching hospital in the Netherlands identified a significant proportion of patients underwent one or more repeat FNA due to non-diagnostic results (classification Bethesda I) and that there was a high utilization of molecular diagnostics. This discovery resulted in an improvement project aiming to optimize needle selection in FNA. This study aims to assess the impact of the improvement project on Bethesda I classifications, appointment time, and health care utilization.

Methods

The present study is a pre-postintervention study utilizing an interrupted time series analysis of observational data. This study received an exemption from ethical approval by the ethics review board of Leiden University Medical Center (nWMODIV2_2024009).

Context

The VBHC care pathway for thyroid cancer is multidisciplinary and provides preoperative analysis, surgery, postoperative treatment, radioactive iodine treatment, and follow-up care. Since 2017, the pathway has been part of a VBHC implementation program, working with a core VBHC team of medical specialists, improvement coaches, financial advisors, researchers, and IT specialists. This team developed a dashboard displaying outcomes and costs to guide continuous improvement of care delivery in plan-do-check-act cycles. Cost data revealed diagnostics was one of the major cost drivers within the care pathway (Fig. 1A). A benchmark of the costs of the expected diagnostic costs (according to the care pathway's diagnostic workup) and the observed costs showed a high variation of diagnostic use among individual patients (Fig. 1B). A significant proportion of patients underwent one or more repeat FNA due to non-diagnostic results (classification Bethesda I) and there was a high utilization of molecular diagnostics. These findings resulted in the consequent improvement project targeting needle selection in FNA.

Intervention

In the preintervention period, sonographers used a conventional syringe needle (21G) to perform FNA per standard practice. This was changed to a Modified Menghini-type needle (Biomol, 20G) needle containing a mandrel in the postintervention period. Using a Modified Menghini-type needle needle, a thyroid nodule is punctured when the mandrel is inside the nodule. The mandrel is then retracted, creating a vacuum and allowing the sonographer to move the needle through the entire nodule with an 'apple coring' motion before withdrawing. The advantage of this needle to a conventional syringe needle is that it prevents contamination of the derived material by blood and tissue that is in between the skin and thyroid nodule and more cells can be sampled. Before implementation, sonographers received training in the use of the Modified Menghini-type needle needle from an expert radiologist. After completing the training and practicing on a phantom, the Modified Menghini-type needle needle was adopted by the sonographers in October 2021. The only change in the entire diagnostic workup was the needle; smear technique and other methods remained unchanged. The samples obtained both pre- and postintervention were considered cytological material and fixed by buffered formalin and embedding in paraffin.

Participants and data sources

Patients were included if they presented with a thyroid nodule at the care pathway between July 2020 and May 2022, were 18 years or older, and underwent FNA performed by a specialized sonographer. Patients were excluded if FNA was performed on thyroid tissue with no discernable nodule or if FNA was performed by a radiologist (in training). Data was retrospectively collected from radiology and pathology reports and financial

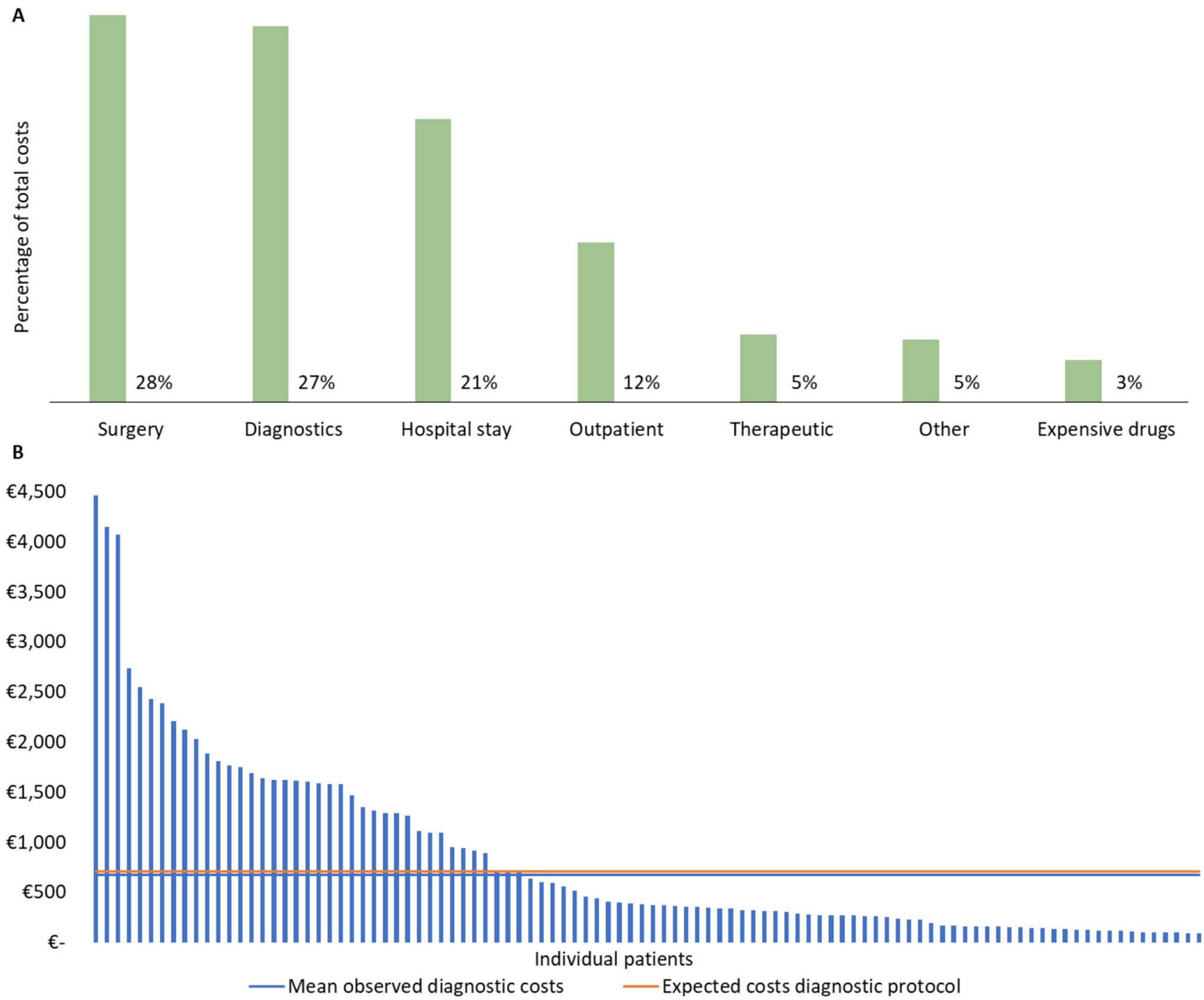

Fig. 1 (**A**) Share of total costs for major cost categories, and (**B**) benchmark of observed versus expected diagnostic costs and variation of costs across individual patients

administration of the institue. The financial administration registers health care utilization at the individual patient level by coupling care activities, including their date, to costs. These costs are derived using activity-based costing (ABC). ABC allocates direct and indirect costs based on distinguishable care activities [12].

FNA characteristics and outcomes

Outcomes collected for each FNA included TI-RADS classification [13], composition and maximum size of the nodus (in mm), number of attempts, number of nodules, sonographer performing the FNA from radiology reports, and Bethesda I-VI classification from pathology reports according to the 2017 Bethesda System for Reporting Thyroid Cytopathology [11]. The TI-RADS categories were: (1) normal thyroid tissue, (2) benign lesion, 3), probably benign lesion; 4) suspicious potential malignant lesion, 5), probable malignant lesion. The Bethesda classifications were: (I) nondiagnostic; (II) benign; (III) atypia of undetermined significance; (IV) follicular neoplasm; (V) suspicious for malignancy; and (VI) malignant.

Health care utilization

Health care utilization data in the first patient year following FNA was collected, including diagnostics, treatment, and follow-up within the care pathway. Diagnostics were divided into an initial diagnostic workup– which included simultaneous FNA, lab tests, ultrasound of the neck, and potentially needle biopsy and histology– and follow-up diagnostics in case of cancer or a nondiagnostic outcome (Bethesda 1). Follow-up diagnostics consisted of additional diagnostic workup, pathology, and/or imaging. Costs were updated to 2024€ with the health care sector-specific consumer price index provided by the Dutch Bureau for Statistics [14]. Health care utilization data was coupled to radiology reports on the patient level. A random sample of 15% of financial data was reviewed to crosscheck whether FNA was registered as a care activity and on the same date as FNA was registered in the radiology reports. Patients with no FNA registered in the financial data were excluded from the analysis of health care utilization. In the healthcare utilization analysis, patients who underwent FNA in both the preintervention and postintervention period were only included in the preintervention group.

The unit cost of FNA in the preintervention period was derived from the ABC model of the hospital. The postintervention unit cost of FNA was estimated under the assumption that FNA costs consist of the costs for the needle(s), plus other costs proportional to the duration of the procedure: first, the cost of a syringe needle (€0.99) was subtracted from the total preintervention FNA unit cost, which was then divided by the duration of an FNA appointment (30 min.) to estimate the FNA unit cost per minute. This FNA unit cost per minute was multiplied by the duration of an FNA appointment postintervention. This duration was estimated as the duration of one FNA appointment (30 min.) minus the difference in the number of puncture attempts pre-postintervention*2.5 min (the estimated average duration of an additional puncture attempt). Then, the current cost of a Modified Menghini-type needle needle (€22) was added to the unit cost.

Statistical analysis

FNA characteristics and Bethesda classifications were analyzed at the level of FNA, and health care utilization was analyzed at the patient level. We first used descriptive statistics and univariate analyses to describe preintervention and postintervention differences. Continuous variables were described as means with standard deviations and analyzed by the independent sample's t-test for (un)equal variance. Categorical variables were described as proportions and analyzed by Fisher's exact test due to the small expected cell count for some variables. The primary outcomes of Bethesda I classification (nondiagnostic) and health care utilization were assessed over time using interrupted time series (ITS) analysis. All ITS models consisted of three model terms: (1) a linear trend over time (in months), (2) a change in level between the preintervention and postintervention period, and (3) a change in linear trend over time (in months) between the preintervention and postintervention period. We used generalized linear models of a binomial family with a logit link function for Bethesda I classification as binary outcome, and a Gaussian family with identity link function for health care utilization in 2024€ as continuous outcome. The analysis of Bethesda I classification was additionally adjusted for sonographer ID using four dummy variables. For all statistical analyses, a p-value below 0.05 was considered statistically significant. Statistical analyses were performed with R studio (version 4.3.1).

Results

In total, 345 FNA in 224 patients were included in this study. In the preintervention period from 1 July 2020 until 11 October 2021, 247 FNA in 155 patients were included, and in the postintervention period from 12 October 2021 until 9 May 2022, 98 FNA in 69 patients were included (Table 1). During the preintervention period, 64% ($n=99$) of included patients underwent only one FNA and postintervention 67% ($n=46$). FNA were independently conducted by five sonographers in the preintervention period and four in the postintervention period. In the patient-level analyses of health care utilization, 18 out of 224 patients were excluded because no FNA or needle biopsy was registered as care activity in their health care utilization data.

The number of biopsies and FNA per month were roughly similar in the postintervention period (98 FNA/7 months = 14.0 FNA per month) and preintervention period (247 FNA/16 months = 15.4 per month). The mean number of puncture attempts per FNA appointment was significantly lower in the postintervention period (independent sample's t-test pre-post mean (SD): 1.7 (0.6) vs. 1.2 (0.5), $p<0.001$). Implementation of the Modified Menghini-type needle needle was thus associated with an average 4% (1.25 min) decrease in appointment time of the previous 30-minute appointment. Combining the time saving with the higher cost of the Modified Menghini-type needle needle resulted in an FNA unit cost of €160.17 postintervention, compared to an FNA unit cost of €142.61 preintervention.

Univariate analysis of Bethesda classifications (Table 1) shows 45% ($n=109$) of FNA resulted in classification Bethesda I (non-diagnostic) in the preintervention period and 27% ($n=26$) Bethesda I postintervention. Classification of Bethesda II increased by 13% points in the postintervention period, from 26% ($n=63$) to 39% ($n=38$), and classifications III-VI varied by a range of 1 to 2% points. These differences were statistically significant (Fisher's exact test, $p=0.02$).

Figure 2A shows the quarterly frequency of Bethesda classifications I-VI during the study period. In the interrupted time series analysis (Table 2), we estimated a significant 81% level decrease in the odds of Bethesda 1 classification following FNA (OR (95% CI) 0.19 (0.05;0.58)), and a 78% level decrease after correcting for sonographer (OR (95% CI) 0.22 (0.06;0.71)). There was no significant change postintervention in the trend of the monthly change in odds of Bethesda 1 classification relative to the baseline trend (OR (95 CI%) 1.09 (0.95;1.26)).

Table 1 FNA characteristics

	Total	Preintervention	Postintervention	*p* value[a]
FNA, n	345	247	98	
Patients, n	224	155	69	
Frequency of FNA per patient, n (%)				0.81
1	138 (62)	99 (64)	46 (67)	
2	55 (25)	36 (23)	18 (26)	
3	18 (8)	9 (6)	4 (6)	
4	10 (4)	8 (5)	1 (1)	
5	1 (0)	1 (1)	0 (0)	
6	2 (1)	2 (1)	0 (0)	
FNA per sonographer, n (%)				< 0.001
#1	106 (31)	71 (29)	35 (36)	
#2	47 (14)	47 (19)	0 (0)	
#3	56 (16)	37 (15)	19 (19)	
#4	101 (29)	76 (31)	25 (26)	
#5	35 (10)	16 (6)	19 (19)	
Puncture attempts per FNA, mean (SD)	1.6 (0.6)	1.7 (0.6)	1.2 (0.5)	< 0.001
FNA unit costs, €		142.61	160.17	
TI-RADs, n (%)				< 0.001
1	12 (5)	12 (7)	0 (0)	
2	20 (8)	15 (9)	5 (5)	
3	94 (35)	50 (29)	44 (46)	
4	119 (45)	80 (47)	39 (41)	
5	20 (8)	13 (8)	7 (7)	
Max. diameter of nodule (mm), mean (SD)	24.5 (14.7)	22.8 (13.8)	28.9 (16.1)	0.001
Bethesda classification, n (%)				0.02
I	135 (40)	109 (45)	26 (27)	
II	101 (30)	63 (26)	38 (39)	
III	46 (14)	33 (14)	13 (13)	
IV	43 (13)	29 (12)	14 (14)	
V	3 (1)	2 (1)	1 (1)	
VI	12 (4)	7 (3)	5 (5)	

[a] *P* value for pre-postintervention comparison using independent samples t-test for continuous data, Fisher's exact test for categorical data, and log-rank test for time to event data. Missing data: Bethesda classification $n = 5$ (pre $n = 4$ and post $n = 1$), TI-RADS $n = 79$ (pre = 76 and post $n = 3$). Abbreviations: FNA, fine needle aspiration; n, number; SD, standard deviation

Figure 2B shows the mean monthly costs per patient for the diagnostic workup and all other care costs over time (in $n = 206$ patients). In the ITS analysis of health care utilization (Table 2), we identified no level change or change in the postintervention monthly trend for both the costs of the diagnostic workup and all other care costs. Table 3 presents the disaggregated health care utilization per patient, for all care categories in both the preintervention and postintervention periods. The mean costs of the initial diagnostic workup per patient were €549 (SD€256) in the preintervention period and €504 (SD€227) postintervention. The difference of €45 was not statistically significant (independent sample's t-test for unequal variance, $p = 0.21$). Total costs of care were €5134 (SD€5743) preintervention and €5949 (SD€6334) postintervention ($p = 0.38$).

Discussion

Integrating the VBHC principles into thyroid cancer care has the potential to reduce unnecessary care procedures and improve the value of care to the patient [4]. This study aimed to evaluate the impact of needle selection in FNA in a VBHC pathway for the diagnosis of thyroid nodules. We hypothesized implementation of a Modified Menghini-type needle needle instead of a standard syringe needle was associated with a lower proportion of nondiagnostic (Bethesda I) results, resulting in less delay in the care pathway, and less health care utilization of downstream diagnostics. The results showed that the implementation of the Modified Menghini-type needle needle was associated with a significant reduction in the odds of Bethesda I classification during FNA. In addition, we estimated a 4% reduction in appointment duration due to fewer puncture attempts per FNA. Use of the Modified Menghini-type needle needle was associated

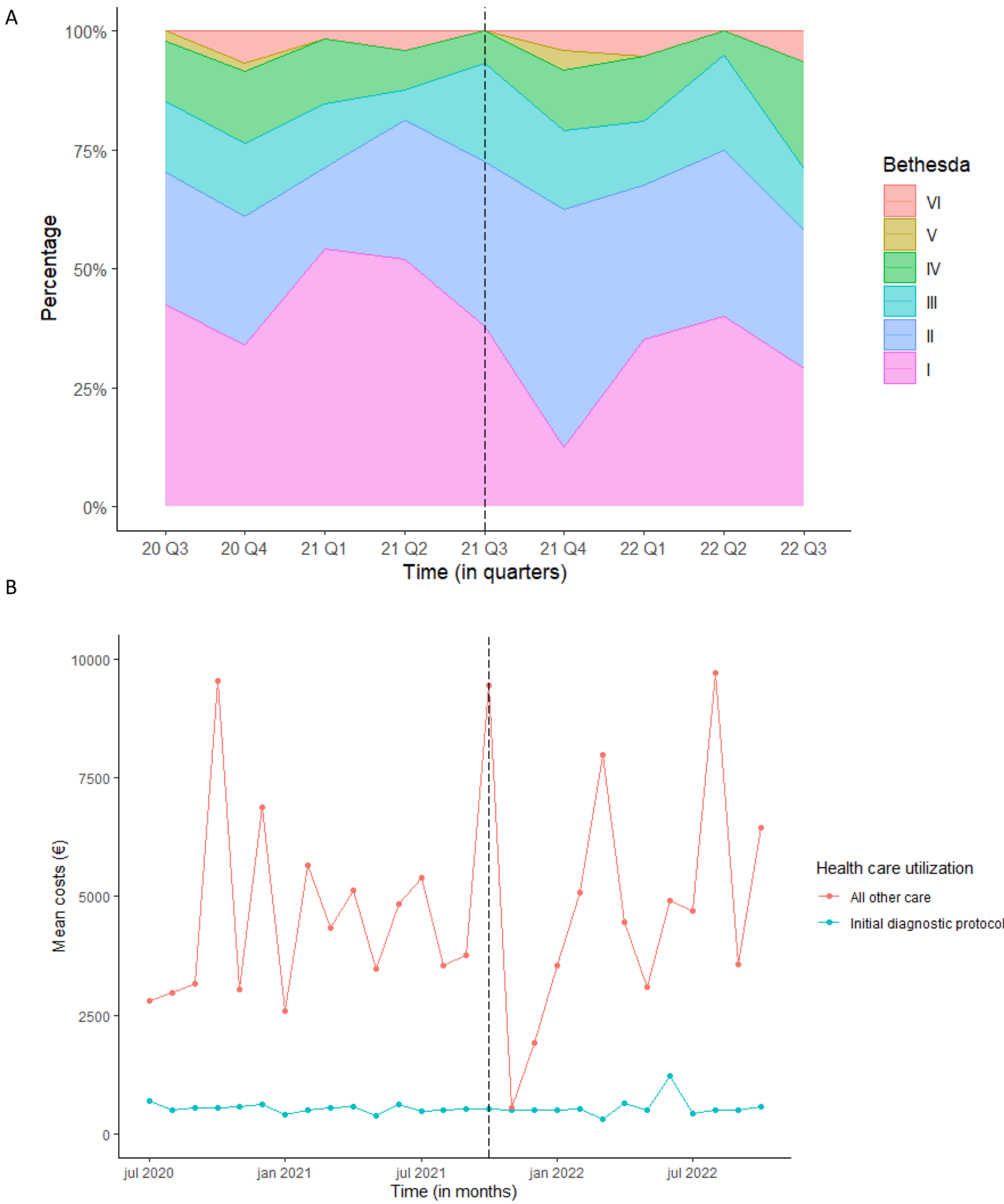

Fig. 2 (**A**) Percentage of Bethesda I-VI classifications per quarter ($n = 340$ FNA), and (**B**) mean monthly costs per patient for diagnostic workup costs and all other care ($n = 206$ patients). Preintervention period before and postintervention period after the dashed lines

Table 2 Interrupted time series analysis of Bethesda classifications and health care utilization

		Preintervention trend (95% CI)	*p* value	Intervention (95% CI)	*p* value	Postintervention trend (95% CI)	*p* value
Bethesda classifications, FNA-level analysis (*n* = 340)							
Bethesda I, change per month in odds	Crude	1.01 (0.95;1.08)	0.66	0.19 (0.05;0.58)	0.005	1.09 (0.96;1.26)	0.20
	Corrected for sonographer	1.01 (0.95;1.08)	0.72	0.22 (0.06;0.71)	0.01	1.09 (0.95;1.26)	0.21
Health care utilization, patient-level analysis (*n* = 206)							
Initial diagnostic workup, change per month in €		-7 (-17;3)	0.17	-8 (-152;135)	0.91	11 (-7;28)	0.23
All other care, change per month in €		59 (-176;293)	0.63	476 (-2976;3927)	0.79	-78 (-498;341)	0.72

Abbreviations: CI, confidence interval

with an additional cost of €17.56 per FNA appointment, but there was no change in initial diagnostic costs or overall health care utilization in the first patient year. This study illustrates that routine measurement of outcomes and costs can drive the identification and evaluation of improvement projects in VBHC for thyroid cancer care.

In our study, we found nondiagnostic (Bethesda I) results in 45% of FNA preintervention and 27% postintervention. Although studies from research institutions generally report a good accuracy of thyroid FNA despite its objective pitfalls, large international surveys indicate that the accuracy may be much lower in regular institutions in both Europe and the US [15]. The general proportion of nondiagnostic results reported in the literature is around 30% [10, 16, 17], meaning the proportion of nondiagnostic results in our institution was relatively high and is now acceptable.

In terms of the costs of the intervention, the Modified Menghini-type needle needle was more expensive (€22) than the standard syringe needle (€0.99). However, we estimated time savings of 4% (1.25 min) per FNA due to the reduction in the number of punctures per FNA following Modified Menghini-type needle implementation. In general, two punctures per nodule are recommended for FNA [18, 19] and in our study, there were on average 1.7 punctures in the preintervention period. In the postintervention period, 1.2 punctures per FNA sufficed. This reduced the €21.01 difference in cost between both types of needles to €17.56 per FNA. Future widespread implementation of the Modified Menghini-type needle needle also allows for price negotiations with the manufacturer, potentially reducing the additional cost.

In this study, we estimated a mean cost of €153 of FNA in the initial diagnostic workup and overall mean health care utilization in the first patient year of €5387 per patient. The main cost drivers were treatment and hospitalizations. In general, comparison of costs across contexts is difficult, as illustrated by a study on the cost disparity of thyroid cancer care in the US and France [20]. A 2024 US study on FNA reported a mean cost of FNA of 349 US dollars [21]. A previous study from the Netherlands on the costs of thyroid cancer care is from 2004 [22]. This study reported a mean cost of €3311 for benign workup at the time and also reported surgery and hospitalizations were the major cost drivers.

Strengths and limitations

This study has both strengths and limitations. A major strength is the use of a hospital-wide costing model that provides the actual cost of care a the patient level. This allowed us to include the costs of the diagnostic workup, as well as treatment and follow-up. Our study also has limitations. First, this study reports an uncontrolled interrupted time series due to the lack of a control group, and thus counterfactual. This means we can form no causal conclusions on the impact of the Modified Menghini-type needle needle on Bethesda I classifications and interpretation of the results should be approached with caution. Furthermore, VBHC adapts the perspective of the patient by measurement of both patient-relevant outcome measures (PROMs) and experience measures (PREMs) [1], but these were not routinely collected in the thyroid cancer care pathway. Future research should include the perspective of the patient, for example by combining relevant outcomes, such as quality of life, and costs to assess the value of thyroid cancer care [23].

Practical implications

In general, there is a great need for cost-effective and risk-adapted approaches to the management of thyroid cancer [10], since only 5–10% of thyroid nodules are clinically diagnosed as cancer [7, 9] and the overall survival is favorable (5-year survival of patients diagnosed between 2015 and 2019 in the Netherlands was 85% [24]). Further studies are required to improve the existing thyroid management systems and new clinical tools are essential to prevent unnecessary workup and management [25].

Table 3 Univariate analysis of health care utilization (in 2024€)

	Total ($n=206$)			Before ($n=142$)			After ($n=64$)				
	%	**Mean, €**	**Mean, SD**	**%**	**Mean, €**	**Mean, SD**	**%**	**Mean, €**	**Mean, SD**	**Mean diff. €**	**p value**
Consultations	**95**	**485**	**416**	**96**	**494**	**426**	**94**	**465**	**397**	**-28**	**0.65**
Initial diagnostic workup		**535**	**247**		**549**	**256**		**504**	**227**	**-45**	**0.21**
FNA	90	153	72	92	154	72	88	153	72	-1	0.91
Lab	46	10	17	42	8	13	55	14	22		
Ultrasound	90	137	70	92	143	72	88	122	65		
Needle biopsy	90	236	124	91	244	133	89	216	102		
Diagnostic follow-up		**227**	**264**		**225**	**259**		**232**	**276**	**7**	**0.86**
FNA	27	46	80	26	44	79	28	50	85		
Lab	51	25	53	49	23	50	56	29	58		
Ultrasound	54	88	95	56	88	91	50	88	103		
Needle biopsy	28	69	119	27	70	122	28	66	112		
Pathology		**972**	**1347**		**940**	**1306**		**1042**	**1442**	**102**	**0.63**
Molecular diagnostics	37	435	630	37	425	614	36	458	671		
Resection biopsy	19	65	137	17	56	128	25	85	153		
Panel oncogenen NGS	37	470	681	37	459	663	36	494	725		
Frozen section	0	2	22	0	0	0	2	5	40		
Imaging		**111**	**312**		**117**	**343**		**97**	**232**	**-20**	**0.61**
CT	10	43	156	11	50	177	9	28	93		
PET-CT	11	57	220	10	58	237	13	56	178		
SPECT	4	11	53	4	10	51	5	13	58		
Treatment		**1152**	**2492**		**925**	**2216**		**1654**	**2975**	**729**	**0.08**
Hemithyroidectomy	12	735	2022	10	574	1742	17	1092	2514		
Total resection without lymphnodes	4	245	1220	4	222	1165	5	295	1342		
Total resection incl. neck lymph nodes	2	131	935	1	95	800	3	211	1186		
Radioactive iodine	6	41	180	4	34	170	9	56	201		
Hospital stay		**1391**	**3337**		**1356**	**3389**		**1468**	**6334**	**112**	**0.82**
Hospital stay	31	1281	3096	30	1237	3121	31	1378	3063		
Outpatient visit	4	21	110	5	25	124	3	12	69		
ICU	4	89	500	4	94	517	3	78	463		
Total		**5387**	**5929**		**5134**	**5743**		**5949**	**6334**	**815**	**0.38**

[a] Independent samples t-test for unequal variance pre- postintervention comparison. Abbreviations: SD, standard deviation; FNA, fine needle aspiration; ICU, intensive care unit

Besides a change in the type of needles [26], there are other strategies to improve the diagnostic yield of FNA. One is rapid onsite evaluation (ROSE) of the material derived from FNA, preventing repeat FNA procedures for patients. A meta-analysis by Witt et al. shows ROSE improves the adequacy of FNA and that sites with lower initial adequacy may benefit the most [27]. Second, performance may be improved by analysis of tumor markers [15] or with the use of AI, although the value of AI for thyroid diagnostics has yet to be determined [28]. In addition, the adequate use of molecular diagnostics may improve diagnostic yield and prevent unnecessary surgery [29, 30]. Finally, studies also suggest core-needle biopsy may yield a high proportion of diagnostic results than fine needle biopsy [31, 32].

Conclusion

This study demonstrates that measuring outcomes and costs in VBHC can drive the continuous improvement of care delivery. The implementation of a Modified Menghini-type needle needle in FNA resulted in increased adequate diagnostic results, time savings during FNA, and no changes in diagnostic and care costs. Future research should investigate the long-term effects of improved FNA performance, and other ways to avoid unnecessary procedures to enhance the value of thyroid nodule diagnostics and management.

Acknowledgements
Not applicable.

Author contributions
Conceptualization: L.W., M.S., M.T.; Methodology: E.A., W.B.; Formal analysis and investigation: E.P., N.S.; Writing - original draft preparation: E.P.; Writing - review and editing: all authors. Supervision: M.T., W.B.

Funding
This study received internal funding from the Value-based Health Care program of Leiden University Medical Center.

Data availability
The data that support the findings of this study are available upon reasonable request from the corresponding author, EP. The data are not publicly available due to the commercially sensitive nature of the data.

Declarations

Ethical approval and consent to participate
This study was reviewed by the medical ethics committee of the LUMC, Leiden, the Netherlands, and received an exemption from ethical approval (N19.116).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Received: 21 October 2024 / Accepted: 17 February 2025
Published online: 17 April 2025

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