**Piloting of a decision aid for recurrent tonsillitis**

**Abstract**

Objective

Currently, there is no adult specific decision aid (DA) to support decision making around recurrent tonsillitis. This study intends to address this gap by piloting a prototype DA.

Design

Randomised clinical trial

Setting

Single centre trial at a tertiary otolaryngology department.

Participants

43 patients were randomised to either the DA or Treatment as Usual (TAU) group.

Main Outcome Measures

*Primary objective:* To measure how patients rate the quality of their decision-making experience at the time of the decision and at follow up (SURE scale).

*Secondary objective:* The level of decisional satisfaction at the time of the decision and at follow up; and to explore the numbers of people opting for surgery from each study condition. (SHARED tool and patient feedback)

Results

*Quality*: This study demonstrates no statistically significant difference in the degree by which patients rate the quality of their treatment decision between DA and TAU, both at baseline (P = 0.553) and follow-up (P = 0.062).

*Satisfaction*: This study showed a statistically significant level of decisional satisfaction at the time the decision was made for Qu2 of the shared tool (U = 113, P = 0.026). No other significant difference was found between participants who received the DA and TAU.

Conclusion

The DA is an acceptable and useful tool which could be incorporated into the pathway for recurrent tonsillitis, helping to eliminate physician implicit bias. However, preliminary qualitative evidence from this pilot study does not suggest that inclusion of the DA improves the quality of decision making.

Keyword: Tonsillitis, Tonsillectomy, Decision aid, Surgery, Sore throat

Key Points:

* Decision aids can be a useful tool in aiding patients decided between surgical and non-surgical intervention for recurrent tonsillitis in adults.
* Decisions aids may be a useful tool in eliminating physician implicit bias.
* Decision aids do not demonstrate increased quality of decision making or decisional satisfaction versus TAU in relation to the treatment of recurrent tonsillitis in adults.
* Decision aids may allow patients to discuss risk and benefits in greater detail with their surgeon if provided prior to their appointment.

**Introduction**

Early in our medical education we are taught the importance of adopting a holistic, patient-centred approach in the treatment of our patients. An important aspect of this, is being aware of patients’ values and accommodating such values whilst considering healthcare options. However, before any decision can be made, informed consent is required. There are three fundamental criteria that must be met for informed consent, lack of coercion, competence and being adequately informed [1]. Unfortunately, patients can at times feel they lack this autonomy within the decision process around their treatment. Even with autonomy a patients decision making can be influenced by the clinical setting and how a health issue or treatment option is presented. Furthermore, a patient’s decision may be based on their own experiences or circumstances. Evidence indicates that when fully informed, patients choose different treatments [2]. Yet, a recent survey demonstrated, that even when presented with the different treatment options, only 64% of patients asked about the pros and cons of each treatment [3]. It is important to remember that there are large differences between what patients want, and what healthcare professionals thinkpatients want. Thus, communication is key in understanding a patient’s values, the impact the condition is having on the patient’s life and what treatment option may best to support a positive change for the patient, whilst also considering what is an acceptable risk for the patient.

Shared decision making (SDM), empowers patients within the decision-making process [4]. SDM can be defined as a collaborative process between patient and clinician involving: 1) Information Exchange – identifying patient values, treatment options offered, risks and benefits discussed; 2) Deliberation – patient preferences are considered against the risks and benefits; 3) Implementation – treatment of choice undertaken [4]. Thus, the application of SDM allows patients to make an informed choice. To further assist this, support tools such as a decision aid (DA) can be utilised [5]. Such tools can be used to provide a platform in which SDN can be delivered, promoting collaborative communication around the various treatment options available [6; 7]. Thus, creating greater opportunity for unity between the patient and healthcare provider, during the decision-making process.

One area in which SDN and DAs may benefit patients, is within adult tonsillectomy. In 1998, the Scottish Intercollegiate Guidance Network (Sign) introduced new guidelines to improve patient selection for tonsillectomy, whilst reducing the potential harm from complications [8]. The new guidelines stipulated that to undergo tonsillectomy, one should have experienced seven or more well documented, clinically significant episodes of tonsillectomy within a one-year period, or five or more such episodes within the previous two years, or three or more such episode within the previous three years [9]. As predicted, the number of tonsillectomies performed since then has reduced dramatically [8]. Furthermore, in the year 2000 there was a shift from multiple use to single use tonsillectomy instruments due to the theoretical risk of prion transmission from patient to patient [8]. The rising costs resulted in a further reduction in tonsillectomies being performed [9]. At the same time, retrospective studies demonstrated a significant rise in hospital admissions related to tonsillitis in patients who had not undergone tonsillectomy [10]. However, the increasing hospital admissions demonstrated may in fact off set the supposed savings made by reducing the number of tonsillectomies performed. A Cochrane review demonstrated that although there were reasonable levels of evidence for tonsillectomy within the paediatric population, for adults this was not the case [11]. This has since been challenged with the NATTINA trial, which has demonstrated early tonsillectomy is both clinically and cost effective in adult recurrent tonsillitis [12].

Despite, tonsillectomy being shown to be an effective approach for adult recurrent tonsillectomy, it may not be the most appropriate for each patient. It is important to remember other aspects may influence a patient’s decision, including but not limited to financial implications, work absences, psychological and emotional impact [13].

This study aims to address this gap through implementing a novel DA. The goal is to not only highlight the pros and cons of each clinical management plan, but also incorporate patient values, supporting a more overt discussion between the patient and the clinician.

Objectives

*Primary objective:* To measure how patients rate the quality of their decision-making experience at the time of the decision and at follow up, either with a DA or in TAU. (SURE scale).

*Secondary objective:* To assess the level of decisional satisfaction patients feel at the time of the decision and at follow up; and to explore the numbers of people opting for surgery from each study condition. (SHARED tool and patient feedback)

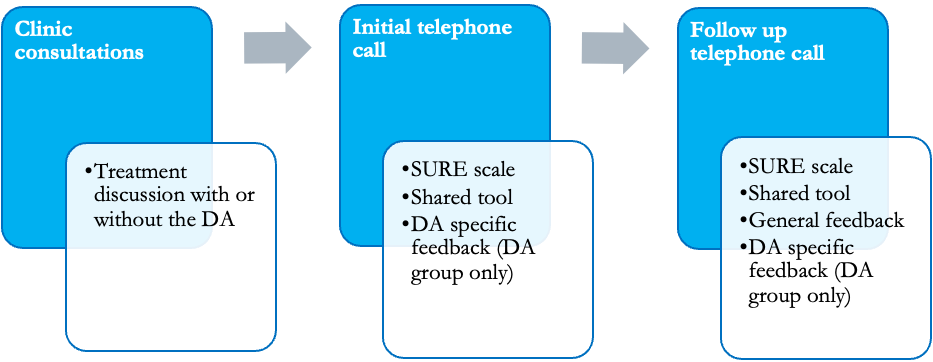
**Methods**

Study design and setting

Figure 1 outlines the study design whereby a single centre pilot randomised controlled trial investigating the effectiveness of a novel DA for treatment selection in adults experiencing recurrent tonsillitis. Having only a single ENT consultant limited the risk of clinician effect on results.

A draft DA for adults with tonsillitis was developed based on a review of the literature with input from ENT clinicians and psychologists. Feedback on the draft DA, to determine its clinical utility, was also sought from patients who had recently attended the ENT clinics for tonsillitis within NHS **“Blinded to insert”.** Based on this feedback, some amendments were made to the draft to produce the final prototype DA that was used for the study.

Figure 1: *Study Design*



Recruitment

All NHS **“Removed to anonymise”** patients currently under the care of ENT, undergoing treatment for recurrent tonsillitis and not participating in any ongoing research trials were eligible. The ENT consultant involved in the trial identified and consented all participants. 43 Participants with recurrent tonsillitis were recruited to attend the ENT an outpatient clinic. Exclusion criteria included any patients under the age of 16 years old and any who did not meet the SIGN guidelines [14].

Randomisation

The study protocol was approved by the NHS Research Ethics Committee.

Participants were allocated to either the Treatment as Usual group (TAU) or the DA through alternative allocation to each group, DA (n=22) or TAU (n=21), by the ENT clinical administrator during the process of sending out clinic letters. Blinding was not possible as the ENT consultant utilised the DA during the discussion around treatment options with the participants of the DA group. However, participants were allocated study identification numbers to limit their responses being directly identifiable.

Intervention

Participants from both groups followed the same study procedure, with the exception of receiving the DA or TAU, along with usual clinic correspondence and the study information sheet.

Whilst attending the clinic, the consultant discussed the treatment options either with or without the DA according to the randomisation. A researcher planned to contact the participants by telephone within one week of the consultation to gather baseline measures. However, the average time for contact was two weeks after. During the phone call the following questionnaires were utilised: Tonsillectomy outcome inventory, SURE scale and Shared tool. Furthermore, feedback on the DA was collected for those within the DA group.

Follow-up data was collected at different time points according to whether the participant chose surgery or conservative treatment options. For both the DA and TAU groups, patients who chose surgery were due to be followed up at 1 month after their surgery date. However, the average follow-up time was 1.5 months after the consultation. Patients from the DA and TAU groups who did not choose surgery were due to be followed up at 4 months after their initial clinic consultation, although the average was 4.6 months (Figure 2).

Outcomes

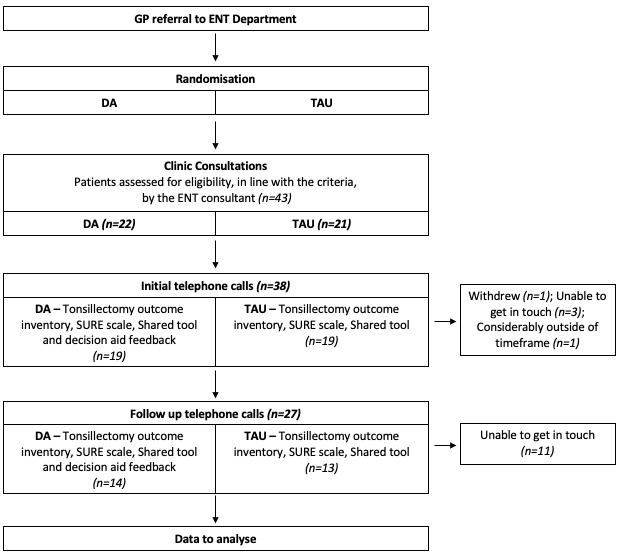
The primary objective of this study was to determine the degree by which patients rate the quality of their treatment decision. Both at the time the decision was made and at follow up, either with a DA or in TAU. This was measured using the SURE scale [15]. A 4-item rating measure with scores ranging from 0, *extremely high decisional conflict*, to 4, *no decisional conflict.*

Secondary to this outcome, was to assess the level of decisional satisfaction the patients felt at the time of the decision and at follow up. Decisional satisfaction was measured by the Shared tool [16]. A 4-point scale measure that contains 8-items consisting of statements about decision making experiences where responses to the statements range from *agree strongly* to *disagree strongly*. A further secondary outcome was to explore whether the DA influenced the numbers of people opting for surgery. Other outcomes of interest included acceptability of the prototype aid, measured through participant feedback.

Statistical analysis

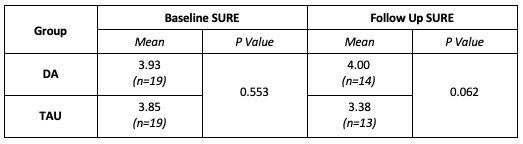
Qualitative statistical analysis of scores at baseline and follow-up was performed using IBM SPSS 25 program. A Mann-Whitney U test was performed to determine if there was a difference in the degree by which a patient rates the quality of their treatment decision between participants who received the DA and those who did not. To determine if there was a difference in decisional satisfaction between participants who received the DA and those who did not, a Mann-Whitney U test was performed. A chi-square test of independence was performed to analyse any associations between participant group and their treatment decision.

**Figure 2**. Flow diagram of the study



**Results**

This study demonstrated, no statistically significant difference in the degree by which patients rated the quality of their treatment decision between DA and TAU, both at baseline, P = 0.553 and follow-up, P = 0.062 (Table 1).



**Table 1.** A comparison in the degree by which patients rate the quality of their treatment decision when using a decision aid versus treatment as usual.

Abbreviation: DA, decision aid; TAU, treatment as usual

Table

Description automatically generatedTable 2 revealed a statistically significant level of decisional satisfaction at the time the decision was made (baseline) for Qu2 of the shared tool “*I felt the health professional thought one option was better for me than another”* (Mann-Whitney U, U = 113, P = 0.026). No other significant difference was found at baseline or follow-up between the participants who received the DA and those who did not.



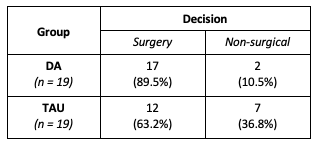
**Table 2.** A comparison in the level of decisional satisfaction for those who received decisional aid versus treatment as usual at the baseline and follow-up.

Abbreviation: DA, decision aid; TAU, treatment as usual

Table 3 demonstrates a higher proportion of patients choosing surgery as a treatment option in the DA group (89.5%) versus the TAU group (63.2%). However, chi-square analysis indicates that this proportional difference between the two groups is not statistically significantly (Chi-square, P = 0.056).

Feedback indicated that all participants within the DA group thought the pilot DA was a comprehensible, acceptable, feasible and desirable tool when discussing treatment options for recurrent tonsillitis.

**Table 3** - A comparison in treatment choice for those who received the decision aid versus those who received treatment as usual



Note: Chi-square analysis - P-value = 0.056

Abbreviation: DA, decision aid; TAU, treatment as usual

**Discussion**

This study explored the use of a pilot DA within the treatment of recurrent tonsillitis and whether such a tool can assist the decision-making process. The results demonstrated no statistically significant difference in the degree by which patients rate the quality of their treatment decision between DA and TAU, both at baseline (Mann Whitney U, P = 0.553) and follow-up (Mann-Whitney U, P = 0.062) or decisional satisfaction. However, when looking at the data sets both the DA and TAU stated they had positive experiences. Therefore, it can be stated the DA is an acceptable tool in the decision-making process but does not demonstrate increased quality of decision-making or decisional satisfaction versus TAU.

Although quantitative statistical analysis showed limited statistical significance to support the use of a DA being superior to TAU alone. Participant feedback from the DA group demonstrated the pilot DA to be easy to understand, providing usual information and thus was an acceptable supplement to TAU alone. Furthermore, several of the participant’s reported feeling that the DA allowed them to assess the risks and benefits of each treatment options giving them insight prior to the consultation with the consultant, allowing them to ask questions during the consultation. Interestingly, a majority of the TAU group believed the consultant provided enough information for them to make a choice. However, when one patient experienced a complication post-surgery, they believed that although the risks had been outlined, they were “touched on bluntly”. Another patient from the TAU group felt they had too much information to process in the consultation, leaving them anxious and with questions unanswered. One such question the participant was particularly anxious about, was risks surrounding antibiotic use. The DA discusses the risks of antibiotic use and thus it may have resolved the anxieties of this participant. From these statements, it may be reasonable to suggest the use of a DA in patients with increased anxiety or complications may help to resolve such issues. However, due to the limitation of a small group of individuals experiencing such issues within this study we cannot make any conclusions around this topic. Further studies should be completed to explore the use of DAs within patients with anxiety, as well as patients who have experienced complications.

The feedback highlighted participants believed the physician favoured non-surgical, over tonsillectomy. The results demonstrated more TAU patients opted for non-surgical management versus the DA group. Thus, suggesting health professionals implicit bias in the discussion around treatment options may have a direct impact on treatment choice. Interestingly, this study was performed prior to the publication of the NATTINA trial which may now influence the approach of the surgeon involved in the trial, favouring tonsillectomy over non-surgical.

More participants choose tonsillectomy within the DA group, suggesting the use of a DA may limit the impact of such bias. This was further supported within the feedback, with a common theme that participants within the DA group felt they were able to make an informed choice when selecting which treatment option was the best for them.

Strengths and limitations

One limitation of the study was contacting participants. The aim for contact at baseline was within 1 week of the consultation. However, for several patients there was a delay in contact, which may have affected their response to the questionnaires and feedback. Furthermore, there was a disparity in the contact time between surgical and non-surgical groups, with surgical groups being contacted at a later stage on average. Once again this may have had an impact on the participants responses.

The small sample size may not have been a representation of the overall population. This was further exacerbated by the loss of several patients during follow-up, this may have skewed the results. Therefore, it would be advisable to expand this study to increase the number of participants.

Having a single ENT consultant participate within the study was previously viewed a strength of the study reducing the risk of clinician effect. However, I believe having a single consultant explain the treatment options may have limited the range in how these treatment options may have been delivered. The feedback demonstrated that there was extremely positive feedback regarding the consultant’s technique in explaining each treatment options. Each physician has a different approach in how they deliver information. Unfortunately, the level in which the consultant delivered this information may not translate to every physician and therefore the results may have been different had a different consultant been involved.

**Conclusion**

The DA is an acceptable and useful tool which could be readily incorporated into in patient pathway for recurrent tonsillitis, possibly in primary care to aid patients making a decision whilst eliminating physician implicit bias. However, preliminary qualitative evidence from this pilot study does not suggest that inclusion of the DA improves the quality of decision-making. To confirm, the study should be repeated with a larger population size.

**Author contribution**

“Removed to anonymise”: data analysis, manuscript preparation, submission. “Removed to anonymise”: Lead Surgeon, concept, data collection, approval of final draft for submission. “Removed to anonymise”: Concept.

**Acknowledgement**

None.

**Funding Information**

The work was supported by NHS “Removed to anonymise” Ear, nose and throat department and Clinical psychology department and The University “Removed to anonymise” but this research did not receive any specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

**Conflict of interest disclosure**

The authors have no conflicts to declare. All co-authors have seen and agree with the contents of the manuscript and there is no financial interest to report. We certify that the submission is original work and not under review at any other publication.

**Ethical approval**

The study was conducted in accordance with the principles of good research practice. In addition to Sponsorship approval, a favorable ethical opinion was obtained from the NHS Research Ethics Committee REC reference: “Removed to anonymise”

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