Addressing the Challenges in Tonsillectomy Research to Inform Health Care Policy
A Review

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IMPORTANCE Eighty-five percent of investment in medical research has been wasted, with lack of effect on clinical practice and policy. There is increasing effort to improve the likelihood of research being used to influence clinical practice and policy. Tonsillectomy is one of the most common otorhinolaryngologic surgical procedures, and its frequency, cost, and morbidity create a clear need for evidence-based guidelines and policy. The first systematic review on tonsillectomy was conducted 40 years ago and highlighted the lack of definitive evidence for the procedure. Since that study, the body of evidence has still not been able to sufficiently inform policy. This review provides an overview of the key challenges in research to inform tonsillectomy policy and recommendations to help bridge the evidence-policy gap.

OBSERVATIONS The challenges in using research to inform policy can be summarized as 4 main themes: (1) non-policy-focused evidence and lack of available evidence, (2) quality of evidence, (3) communication of research findings, and (4) coordinating time frames. Researchers and decision makers should be aware of the limitations of research designs and conflicts of interest that can undermine policy decisions. Researchers must work with decision makers and patients throughout the research process to identify areas of unmet need and political priority, align research and policy time frames, and disseminate research findings. Incentives for researchers should be reorganized to promote dissemination of findings.

CONCLUSIONS AND RELEVANCE It is important to consider why evidence gaps in tonsillectomy research have not been addressed during the past 40 years despite considerable investment in time and resources. These findings and recommendations will help produce research that is more responsive to policy gaps and more likely to result in policy changes.

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A recent series in The Lancet argues that 85% of investment in medical research has been wasted, with lack of effect on clinical practice and policy.1 It is difficult to justify spending limited resources on health research if the research does not inform decisions regarding patient care. Thus, there is increasing effort to improve the likelihood of research being used to influence health policy and clinical practice.2,3

Sore throats cost the National Health Service more than £120 million per year,4,5 and tonsillectomy is one of the most common otorhinolaryngologic surgical procedures in the United Kingdom, with more than 60 000 operations performed annually.4,6 In the United States, more than 750 000 tonsillectomy procedures are performed each year.6,7 Complications of tonsillectomy include pain, bleeding, damage to oral structures, voice change, and rarely death.7 The frequency of the procedure, its cost, and its associated morbidity indicate a need for evidence-based guidelines and policies to guide health care professionals. The current commissioning criteria and clinical guidance for tonsillectomy for sore throat in the United Kingdom are 7 or more episodes in the preceding year, 5 or more episodes in each of the preceding 2 years, or 3 or more episodes in each of the preceding 3 years.9,10 The same clinical criteria are used in the United States.11,12 These policies and guidelines set the criteria for service delivery and therefore have a major effect on the care received by patients. It is important for guidelines and policies to be based on strong evidence so that health care professionals’ decisions are well informed.

The first systematic review and quality assessment for tonsillectomy was conducted 40 years ago.13 That study highlighted the lack of definitive evidence for tonsillectomy, calling for urgent, high-quality research in the area, particularly in view of escalating health care costs and procedure-associated morbidity. Since that review, there have been more than 9000 publications on tonsillectomy. Despite this considerable amount of work, the 2014 Cochrane review14 and the 2010 Scottish Intercollegiate Guidelines Network guidelines15 concluded that the information on adult tonsillectomy is still not sufficiently robust to draw firm recommendations, and although there is more evidence on pediatric tonsillectomy, considerable limitations remain.10,15 Owing to
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These limitations, the Scottish Intercollegiate Guidelines Network guidelines reported that the widely accepted criteria for tonsillectomy were “arrived at arbitrarily,” and the National Health Service England regards tonsillectomies as “procedures of low clinical priority.”

Therefore, despite the considerable amount of research during the past 4 decades, the evidence has not been able to sufficiently inform policy and guidance. To minimize waste in research and improve the care provided to patients, it is important to conduct research that can be used to influence guidance and policy. In this narrative review, we provide an overview on the key challenges for research to inform health policy with reference to tonsillectomy. We also produce recommendations to help bridge the evidence-policy gap.

Methods

A search of the gray and scientific literature from inception to November 2016 was conducted using the MEDLINE, EMBASE, and Google databases on November 10, 2016. The following search string was used: (barriers OR challenges OR difficulties) AND (research OR evidence) AND (health) AND (policy). Reference lists of included articles were screened for relevant citations. Articles were included if they discussed challenges for research to inform health policy.

Discussion

Challenges for Research to Inform Health Policy

During the past 40 years of tonsillectomy research, although positive steps have been made on the evidence available for pediatric tonsillectomy, considerable gaps remain, including limited follow-up, generalizability of findings, and heterogeneity. Evidence gaps in adults are more significant; information on adult tonsillectomy is not sufficiently robust to draw firm conclusions. There is a clear need to build on the existing evidence for pediatric tonsillectomy and to conduct a new trial on adult tonsillectomy to inform guidelines and policy. In this regard, we welcome the ongoing National Randomised Controlled Trial of Tonsillectomy in Adults (NATTINA) trial, which aims to assess the clinical effectiveness and cost-effectiveness of adult tonsillectomy. The current US and UK policy and guidelines for tonsillectomy are based on the 1984 Paradise criteria. However, these criteria were arrived at arbitrarily, the trial included only children who underwent tonsillectomy using the dissection and snare technique, and there were concerns about the balance of participant baseline characteristics. There are therefore legitimate concerns about the generalizability of these criteria to adults and to electro- (bipolar or coblation) tonsillectomy.

It is important to consider why evidence gaps have not been addressed during the past 40 years despite considerable investment in time and resources. The barriers to using research to inform policy can be summarized into 4 main themes: (1) non-policy-focused evidence and lack of available evidence, (2) quality of evidence, (3) communication of research findings, and (4) coordinating time frames.

Non-Policy-Focused Evidence and Lack of Available Evidence

Research is more commonly conducted in areas of academic interest, driven by researchers and clinicians rather than being steered by the information needs of patients and policy makers. It is not surprising, therefore, that despite significant evidence gaps in tonsillectomy research being highlighted 40 years ago, research continues to be performed in areas that do not address these gaps, reducing the ability to make policy decisions. Policy makers ask 3 main questions when developing policy: (1) Does it work? (2) Will it work here? (3) Is it worth it? To help answer these questions, a decision maker must screen a considerable amount of information and ultimately may not find answers. This lack of answers makes it challenging for decision makers to engage with and use the scientific literature to inform policy.

Lack of available evidence constitutes another challenge. For tonsillectomy, there is insufficient evidence to draw firm conclusions on the effectiveness of the procedure, particularly in adults. Despite this gap in evidence, policy decisions must be made, and tonsillectomy for adults has been commissioned nationally. The cost-effectiveness of tonsillectomy is also uncertain, and urgent research is needed in this area. Cost-effectiveness is particularly important to decision makers, and lack of cost-effectiveness evidence makes it challenging for policy makers to allocate resources for tonsillectomy, particularly in times of economic constraint.

Quality of Evidence

Most tonsillectomy research consists of nonrandomized, observational studies. These studies generally report reductions in sore throat, improvements in well-being, and high levels of patient and parental satisfaction after tonsillectomy. However, observational studies, including cross-sectional, cohort, and case-control studies, have several weaknesses that limit their use to inform guidance and policy.

The Box summarizes the main limitations of different study designs in informing health policy.

Box. Main Limitations of Different Study Designs When Informing Health Policy

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Limitations</th>
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</thead>
<tbody>
<tr>
<td>Cross-Sectional Study</td>
<td>Exposure and outcome are assessed at the same time; risk of bias must be assessed</td>
</tr>
<tr>
<td>Cohort Study</td>
<td>Loss to follow-up; risk of bias when assessing outcomes makes it difficult to mask investigators assessing a surgical treatment</td>
</tr>
<tr>
<td>Case-Control Study</td>
<td>Risk of recall and interview bias; selection of control individuals should be similar to that of patients in all aspects other than not having the disease</td>
</tr>
<tr>
<td>Randomized Clinical Trial</td>
<td>Expensive; data collection can be complex; difficulty in capturing long-term outcome data</td>
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</tbody>
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Conflicts of interest, such as associations between industry funding and statistically significant proindustry findings, external validity and generalizability of findings, difficulty in masking surgical treatment arms, and funding and statistically significant proindustry findings, are other important limitations.
Cross-sectional studies\textsuperscript{55-41} have commonly been used to assess factors associated with outcomes after tonsillectomy. For example, Bhattacharyya and Shapiro\textsuperscript{40} assessed associations between socioeconomic factors and complications after tonsillectomy. One of the key limitations with these studies is the exposure and outcome are assessed at the same time; thus, although an association between them can be determined, it is difficult to conclude that the exposure caused the outcome.\textsuperscript{56} Cohort studies\textsuperscript{42-44} have been used to evaluate the effect of tonsillectomy over time. A study by Liu et al\textsuperscript{45} assessed voice performance of pediatric patients after tonsillectomy with or without adenoidectomy. One of the main limitations with this study design is loss to follow-up, particularly when the dropout rate differs in the exposed and nonexposed group.\textsuperscript{56,28} In tonsillectomy research, case-control studies\textsuperscript{46-48} are often used for assessing risk factors for postoperative complications. Such studies\textsuperscript{16,28,29} are at risk of recall and interview bias, with patients who have undergone tonsillectomy (cases) being more likely than control individuals to remember exposures and interviewers likely to interview patients more thoroughly than controls.

Randomized clinical trials (RCTs) are usually considered to be the gold standard owing to their potential to eliminate bias and confounding. However, RCTs also have several weaknesses relevant to policy making.\textsuperscript{29-34,49-52} The Cochrane review by Burton et al\textsuperscript{13} included 7 RCTs to assess the effectiveness of tonsillectomy for tonsillitis in adults and children. These RCTs were graded as providing low- or moderate-quality evidence, and as expected, none of the trials were able to mask children.\textsuperscript{57} These RCTs were only able to provide good information about the effectiveness for tonsillectomy for the first year after surgery and for 6 months after surgery in adults. These weaknesses limit the ability to make confident national policy and guideline decisions.

Communication of Research Findings

Even research that is relevant, robust, and timely may not influence policy if it is not communicated effectively to policy makers.\textsuperscript{53} Research findings are usually disseminated in an academic format via scientific journals and research conferences. Policy makers rarely access these resources, relying instead on the gray literature.\textsuperscript{54,55} There is also a lack of incentive for academics to disseminate their findings to nonacademic audiences\textsuperscript{55}; universities evaluate academics based on number of publications and journal impact factor rather than the influence of their work on policy. Researchers have reflected on their lack of training and experience in communicating their research findings outside the academic arena.\textsuperscript{55,56} Similarly, policy makers have reported difficulties in identifying researchers and institutions to communicate policy requirements.\textsuperscript{55,56}

Coordinating Time Frames

Academic research takes a considerable amount of time to conduct, write, disseminate, and publish. Policy makers, however, frequently work on much shorter time frames, and policy is often the result of fast decision making in response to sudden developments, media attention, parliamentary debates, or public opinion.\textsuperscript{57} Even when not in response to an urgent need, policy needs to work on short deadlines. For example, select committee calls for evidence usually close 1 month from the date the call is announced.\textsuperscript{57} It can be difficult to align research and policy time frames,\textsuperscript{58} and if evidence is published outside policy time frames,\textsuperscript{59} it is unlikely that it will be used to inform policy decisions.\textsuperscript{14} The clinical commissioning policy for tonsillectomy was published in 2013, a year before a comprehensive Cochrane review\textsuperscript{13} on tonsillectomy. Such a comprehensive review may have contributed to policy development; the Cochrane review concluded that although there is insufficient evidence available on the effectiveness of tonsillectomy in adults, there is evidence supporting the effectiveness of tonsillectomy in children. However, the 2013 policy considered tonsillectomy to be a procedure of limited value for adults and children.\textsuperscript{9}

Bridging the Gap Between Evidence and Policy

When using research to inform policy, it is important for researchers and decision makers to be aware of the limitations of research designs and conflicts of interest that can undermine policy decisions and affect the health of large populations.\textsuperscript{60} In response to this challenge, a number of bodies, including Cochrane, the National Institute of Health and Care Excellence, and Health Technology Assessment, have been tasked with independently synthesizing and critically appraising evidence. However, synthesizing and appraising evidence are not sufficient to ensure that evidence is used to inform policy.\textsuperscript{14}

The scientific literature is written mainly by and for researchers, with little consideration given to policy makers.\textsuperscript{3} There is increasing consensus that researchers must work with decision makers and patients throughout the research process to bridge the gap between evidence and policy.\textsuperscript{34,54,56} This collaborative environment will help identify areas of unmet need and political priority while aligning research and policy time frames.\textsuperscript{3} Policy makers should also be included when reporting research findings, such as through stakeholder dissemination workshops or by coauthoring structured executive lay summaries.\textsuperscript{54-56} This collaboration helps present the research findings in an interactive and accessible format and gives policy makers a sense of research ownership, which is crucial for uptake of findings.\textsuperscript{54,61} Reorganization of incentives for researchers can promote dissemination of findings by rewarding the effect made on policy in addition to the number of articles published.\textsuperscript{55} Of importance, collaboration between researchers and policy makers can facilitate the development of policy recommendations that are feasible and take into account political and economic constraints.\textsuperscript{55,56} Policy makers have reported that when involved in the research process, the research was more likely to be used for policy development.\textsuperscript{54,56} Similarly, researchers have commented that by involving policy makers, they were more responsive to policy gaps in their research and their research was more likely to result in policy changes.\textsuperscript{54,56} The GENERATE ENT research agenda\textsuperscript{62} launched by ENT UK represents a step forward by otorhinolaryngologic researchers to develop a national research agenda informed by professionals and patients; however, more progress is required to help bridge the evidence-policy gap.\textsuperscript{63}

Conclusions

It is important to consider why evidence gaps in tonsillectomy research have not been addressed during the past 40 years despite considerable investment in time and resources. Our findings and recommendations will help produce research that is more responsive to policy gaps and more likely to result in policy changes.
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