

The old, the new and the ever-changing view of haemorrhoidal disease research

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VALORIZATION

The process of disseminating scientific knowledge, and making it available for society, is called valorization of knowledge. This chapter describes the valorization potentials of this thesis. The results described in this thesis are relevant for patients, healthcare professionals, the scientific community and the government.

To patients

Patients become more and more empowered, and are eager to learn about available treatment options and the impact of therapies on their quality of life. Besides, there is a growing trend to include patients in advisory groups and decision-making processes to incorporate their opinions and ideas.

This thesis showed that several patient relevant aspects are overlooked if HD treatment is only assessed by traditional doctor's endpoints. In the majority of HD studies treatment success is mainly based on quantitative measurement of parameters such as prolapse, recurrence, complications and duration of operation (1-3). However, in this thesis qualitative interviews with patients showed that beside these traditional endpoints, patients are more concerned about the bothersomeness of the symptoms and the impact of HD on their daily life.

We developed a Core Outcome Set (COS) for HD. Patients participated in its development process. This collaboration between patients and healthcare professionals resulted in a COS with 'Patient Reported Symptoms' as primary endpoint. This outcome should be assessed by a Patient Reported Outcome Measure (PROM). PROMs are questionnaires that measure the patient's experiences regarding health (outcomes) and well-being (4). Several PROMs for HD have been published like the Symptom-based Severity Score of Pucher et al. (5), the Haemorrhoid Severity Score (HSS) introduced by Nystrom (6), the Hemorrhoidal Disease Symptom Score (HDSS), the Short Health Scale HD (SHS) by Rørvik et al. (7) and the Haemorrhoid Symptom Score recently used in the eTHoS trial (8). Yet, these scoring systems have not gained wide acceptance in the clinical and research setting which may be due to a lack of robust development and validation process. Moreover, some questionnaires were not derived from patients' experiences with haemorrhoidal disease. Recently, our research team developed the PROM Haemorrhoidal Impact and Severity Score (PROM-HISS), which is based on the outcomes of Delphi study and qualitative interviews reported in this thesis (9). Apart from symptoms, the PROM-HISS takes impact of HD symptoms on daily life and satisfaction with treatment into account. The above illustrates the impact the research from this thesis has on strengthening the patients' perspective in HD and on inspiring further research on this topic.

To healthcare professionals

One of the deliverables of this thesis is an international guideline. This filled in an existing gap for healthcare professionals. A Dutch survey, published in this thesis, confirmed the need to develop such a guideline as its results showed considerable practice variation in HD treatment in the Netherlands despite the already existing Dutch guideline. Besides the Dutch guideline, other national guidelines for HD are available as well (10-12). In these guidelines, core recommendations are mostly difficult to identify and the documents are long and bulky. Moreover, these national HD guidelines did not follow the AGREE instrument (Appraisal of Guidelines for Research & Evaluation), an international adapted development method (13-16). In this thesis the development of an international, multidisciplinary HD guideline is described incorporating AGREE (13-16) and GRADE (17, 18). We believe this guideline has the potential to contribute to a standardized treatment algorithm for patients to be used by healthcare professionals. Furthermore, this thesis is valuable for healthcare professionals since it revealed new knowledge gaps in the literature of HD. For example, a knowledge gap for the best treatment algorithm in case of recurrent grade II and III HD was discovered. There are no existing randomized trials assessing (cost)effectiveness of different treatment options in patients with this manifestation of HD. Recently, our research group received a grant to conduct a RCT in the Dutch setting (Grant by ZonMw, the Netherlands Organisation for Health Research and Development; <https://www.zonmw.nl/nl/>). This RCT, named the Napoleon Trial, will include patients with recurrent symptomatic HD grade II and III and aims to provide high level evidence regarding the (cost)effectiveness of rubber band ligation versus sutured mucopexy versus haemorrhoidectomy. This study will start inclusion in March 2020 (zorgevaluatie.nl/napoleon-trial).

Therefore, this thesis has not only offered valuable information for current healthcare givers, but also contributes to obtaining further knowledge by new scientific work.

To researchers

For researchers, the development processes of the COS and guideline presented in this thesis might be of interest. The methods and protocols are published in peer reviewed international journals. Such protocols provide researchers a detailed and step by step overview of the development processes which may be insightful for future COS and/or guidelines developments in other clinical fields. Moreover, this development process may also be useful for researchers to recognize the challenges to involve patients and healthcare professionals in a balanced manner in such processes. Another insight from this thesis is that in both the COS and guideline development, the involvement of patients could be optimized. This can be enhanced for example by installing a Patient Advisory Board (PAB). A PAB includes a group of patients experiencing HD. One person can be appointed chairman and representative in the scientific project group, adding the patient's perspective of the PAB. Throughout the process close collaboration

can be maintained with the PAB following a jointly prepared participation plan. Budget should be reserved to reimburse the patient advocates for every meeting. All members of the PAB fulfill the role of partner according to the participation matrix, meaning there is an equal cooperation with the investigators (19, 20).

Moreover, the HD COS in this thesis gives guidance for future researchers as to which minimum set of outcomes should be included in future HD studies. Broad use of the COS in future research will enhance optimal evidence synthesis which will result in future guidelines with higher level of evidence recommendations.

Finally, it is important to emphasize that both a COS and a guideline are dynamic constructs which should be reviewed regularly by researchers based on new evidence. An update will be conducted by our research group. For the guideline this will involve updated searches and assessment of any relevant research topic found in relation to the current recommendations and considerations leading to adaptation and change of the guideline.

To the government

Around the world, health care systems are struggling with rising healthcare costs. As a result, there is an increasing interest in maximizing the efficiency of health care. Annually 50.000 patients are referred to the Dutch hospital because of persistent HD symptoms (21), hence there is a profit to be gained by improving effectiveness and decreasing the budget impact of treatment of HD.

The HD guideline described in this thesis contributes to improving of the cost-effectiveness of care for HD by presenting the best available evidence for each degree of this disease. Moreover, for grade I and II HD RBL is recommended and for grade III and IV HD the traditional haemorrhoidectomy. These are both techniques that are less expensive than sclerotherapy and infrared coagulation (for grade I and II) and stapled hemorrhoidectomy (for grade III and IV).

In the guideline a separate chapter is dedicated to the economic evidence. In our opinion the HD guideline in this thesis could greatly improve the quality of care and reduce treatment costs for HD.

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