

Patient-centred haemorrhoidal disease management

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Impact

To create value from knowledge, the data extracted from this thesis should be made suitable and/or available for social and economic use. This process is referred to as impact and should elaborate on the socio-economic relevance of the research. The findings of the studies described in this thesis aim to impact patients, health care professionals, the scientific community, and health insurance companies.

Patients

As patients become increasingly empowered and eager to take on an active role in the medical decision-treatment process, tools are needed to facilitate the conversation between doctor and patient¹. One of these tools is a patient-reported outcome measure, or PROM in short. PROMs are questionnaires that measure the patient's experiences regarding health and well-being². Several PROMs for haemorrhoidal disease (HD) exist, but generally lack a robust development and validation process. One of the deliverables of this thesis, is a PROM for HD, developed by and for patients with HD, following established guidelines: The PROM-Haemorrhoidal Impact and Satisfaction Score (PROM-HISS). The PROM-HISS was found to be a valid, reliable and responsive measure and thus suitable for research. At the moment, we are employing the PROM-HISS in the electronic patient system of our medical centre to start using this tool in clinical practice. The PROM-HISS is completed by the patient before presenting at the outpatient clinic and the treating physician can discuss the results of the PROM-HISS with the patient to identify subjects that are important to that specific patient. This way, the patient's expectations and experiences function as the cornerstone of the treatment-decision and follow-up, resulting in a more patient-centred approach. Furthermore, for many patients haemorrhoidal symptoms still remain an embarrassing subject in the consultation room³. With the PROM-HISS, we aim to open the conversation about symptoms of HD and dwindle the taboo-image of this disease.

In research settings, the PROM-HISS can ensure that patient-relevant outcomes are included as evidence for the most (cost-)effective treatment for HD. By doing so, the patient himself or herself is at the helm of optimizing healthcare, both for him-, herself as for future HD patients.

All these PROM-related initiatives contribute to a more patient-centred approach in future healthcare. Informing patients and healthcare providers about PROMs and implementing them in daily practice contributes to a change in tomorrow's climate in healthcare, whilst simultaneously exerting a direct impact on the individual patient of today.

Health care professionals

Most studies described in this thesis were conducted in collaboration with various hospitals across the Netherlands. The most significant example of this is the *Napoleon Trial*, where over 20 medical centres were involved. The *Napoleon Trial* is a randomized controlled trial comparing the (cost)effectiveness of rubber band ligation, sutured haemorrhoidopexy and haemorrhoidectomy in

patients with recurrent HD. All three of the treatments are currently standard care and the protocol of the *Napoleon Trial* is presented in this thesis. Nevertheless, this study was prematurely ceased and high-quality evidence could not be distilled from the data. Various other study designs were explored, but were not deemed adequate or feasible at this stage. As a result, there is still no consensus on the most optimal management of HD. The Dutch Surgical Association (NVvH) still acquiesces the current knowledge gap regarding the most effective and cost-effective treatment for (recurrent) HD.

The nation-wide teamwork established for the *Napoleon Trial* has shown the ambition to resolve a research question and laid the base for future collaborations between colorectal surgeons in the Netherlands. Establishing partnerships all around the country facilitates conducting scientific research and contributes to evidence-based guidelines on the most (cost-)effective treatment in HD.

Results of this thesis regarding the sutured haemorrhoidopexy indicate that this procedure is safe and feasible to be used for patients suffering from mainly the prolapsing component of HD, as a worthy alternative to the traditional excisional surgery (haemorrhoidectomy). Furthermore, using the PROM-HISS in clinical practice facilitates the health care professional to discuss themes relevant for the patient. The involvement of numerous (colorectal) surgeons in the studies described in this thesis, enables the uptake and the implementation of the results.

Scientific community

The PROM-HISS which is presented in this thesis resulted from the primary outcome as stated by the Core Outcome Set (COS) for HD⁴. The COS has been developed to inform researchers as to which minimum set of outcomes should be included in future HD studies.

Broad use of the COS and PROM-HISS will decrease heterogeneity in study outcomes and enhance optimal evidence synthesis in the field of HD. We closely followed the statement of the COS in choosing the primary and secondary outcomes of the *Napoleon Trial*. One of the primary outcomes is symptoms as reported by the patient, making use of the PROM-HISS. We strongly recommend using the COS for HD in future studies to inform guidelines for the treatment of HD. Furthermore, the complete process of the development, validation and of a PROM is described in this thesis. These chapters can give guidance to scientific audience interested in performing such a process.

Lastly, the articles presented in this thesis were all published in peer reviewed international journals. Consequently, more attention from the scientific community is drawn to this prevalent and burdensome disease. With more attention comes more awareness to file for scientific grants regarding the treatment of HD. This will result in more high-quality research and an optimized management for patients with HD.

Health care organisations

Both the disease burden and the economic burden of HD are huge. In the United States of America, around 1.4 million individuals sought care for HD in 2014, with an estimated economic burden of about \$800 million annually⁵. In the Netherlands, some 4,500 operations for HD are performed

annually and an unknown equivalent of RBL procedures⁶. With the increasing healthcare costs, health care systems (and organisations) need to fundamentally change and focus on true patient value for money. One of the solutions is to create 'a health system that explicitly prioritizes health outcomes which matter to patients, relative to the costs of achieving the outcome'⁷. This approach is called value-based healthcare (VBHC) and takes patient expectations and experiences as key concepts of care delivery⁸. Using a PROM, such as the PROM-HISS presented in this thesis, can determine the needs of patients, and can consequently attribute to VBHC.

Next to a function in patient-centred healthcare, PROMs such as the PROM-HISS can be used to measure and benchmark internal and external quality of care. Recently, the Zuyderland Medical Centre in collaboration with a health insurance company used aggregated data from a PROM to evaluate the internal quality of several departments within their hospital⁹. PROMs were integrated in the Quest Manager system (Philips VitalHealth) of the electronic patient system of the Zuyderland and digitally communicated with the patient^{10,11}.

In addition, also the use of PROMs in quality monitoring (e.g. benchmarking individual providers, teams, organisations), performance measurement (e.g. comparing healthcare systems) and policy (e.g. pay-for-performance, reimbursement decisions) is increasingly applied and advocated to capture what really matters to patients^{12,13}.

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