Editorial Commentary

Mesh surveillance after hernia repair

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In 2016, Johnson and Johnson recalled their high-volume mesh product Physiomesh because of high failure rates (1). Since then, patients have filed major lawsuits against the company, and the use of mesh in general for hernias has been heavily debated in media (2). Hernias are among the most frequently treated diseases in surgery, and repair with synthetic mesh materials for reinforcement have for many years been considered the gold standard to prevent hernia recurrence (3). There are more than 200 different meshes for hernia repair on the market. Unfortunately, many of these are replaced with upgraded versions before sufficient long-term outcome data have been collected on the previous editions (4). Based on high quality data, there is no doubt that meshes in general reduces the risk for recurrence significantly (5-7). Nevertheless, a mesh is not just a mesh, and properties varies widely between different meshes (8).

Regrettably, and in contrast to drugs, the safety and effectiveness for most medical devices including surgical implants have not been subject to strict experimental or clinical documentation as well as final approval from governmental institutions (9,10). In recent years it has been shown that long-term follow-up after hernia repairs are mandatory in order to evaluate outcome, and that the reduced risk for hernia recurrence, may be on the expense of increased complications over time (6). In particular studies showing significantly poorer outcome from one specific mesh compared with other synthetic meshes, have contributed to the debate about mesh surveillance (11,12). In the wake of this, companies faced million-dollar lawsuits and several mesh products have been with-drawn from the market (13). New regulations demanding more pre-marketing data and continuous post-marketing surveillance in Europe has now been initiated to be fully implemented in 2022 (14). Until now, the FDA requires no post-marketing surveillance (15).

For the mesh industry and the healthcare systems the new regulations raise a number of questions: for instance, what does it take to get a mesh approved? How long follow-up is needed? Will companies stop producing meshes because it becomes un-profitable? What is required for a sufficient surveillance? What do we tell the patients? But most importantly, how should a cost-effective surveillance be performed.

From a research perspective, randomized controlled trials (RCTs) and meta-analyses of RCTs are considered the highest level of evidence (16). Such studies have high internal validity and are easy to reproduce if studies are performed under the same conditions. Unfortunately, hernia patients are very heterogenic and hernia recurrences and mesh-related complications continue to appear after many years (6). As a result, sufficient surveillance after hernia repair in a randomized setting are considered impossible to perform from a research as well as an economical point of view (16). In contrast, studies from clinical databases such as the Danish Hernia Registry and the German HerniaMed have proven to be valuable tools to identify underperforming meshes (17,18).

Interpretation of outcome after mesh repair is complex and requires significant insight since numerous factors are involved e.g., surgeons' skills, type of mesh, type and size of

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hernia, surgical technique and patient co-morbidity. Until know the most common, and easiest to measure, outcome parameter has been recurrence. Outcomes such as acute and chronic pain, and chronic infection, are probably affected by even more variables. Thus, in order to evaluate mesh safety massive data are needed to adjust for a large number of variables. Large registers have high volume potential, but because of the statistical complexity and large numbers of variables results on mesh safety can only be indicative regardless of the register size. Therefore, surgeon's choice of mesh should be supported not only by high volume studies but also on recommendations from surgical societies.

Another issue to be dealt with before evaluating short- and long-term mesh outcome is the lack of consensus on which variables should be assessed and how they should be analysed. In addition, many countries have healthcare systems that rules out long-term patient follow-up. In the Nordic countries, all citizens are given an unique social security number at birth, making it possible to track all contacts to the healthcare system from birth to death (19). Given the opportunity to combine systematic perioperative data from a well-established clinical database with long-term data from nationwide health-related registries, it seems that such registries are the most cost-effective tools for mesh surveillance (17). Since this platform already exists and has proven its worth, the problem to be solved is to define when a mesh can be considered inadequate (11).

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