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Shared Decision Making in Hernia Repair

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Abstract

As the digital age of healthcare is evolving, patients are more aware, educated, and concerned about their surgical options due to access to information. Patients undergoing hernia repair are being exposed to the growing litigious environment surrounding mesh via targeted social media marketing and inorganic search engine optimization (paid SEO). As a result, we elected to implement a shared decision making (SDM) process to give our patients an active role in choosing the reinforcement material used in their repair. A cohort of 142 patients underwent the SDM process with 133 (93.7%) choosing the reinforced biologic repair (ReBAR), 8 patients (5.6%) chose permanent synthetic mesh and 1 patient (0.7%) chose a completely resorbable bio-synthetic mesh. Clinical outcomes have been similar before and after implementation of the SDM process. SDM, as has been shown in other fields of medicine, improved patient satisfaction, patient compliance, and decreased anxiety about the treatment plan. We believe that the implementation of a SDM process in hernia repair surgery will continue to result in increased patient satisfaction, reduce legal exposure, and warrants further investigation as the paradigms in the doctor-patient relationship continue to be disrupted by technology and the internet.

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Introduction

As the digital age of healthcare is evolving, patients are more aware, educated, and concerned about their surgical options due to access to information. This is particularly becoming true for patients undergoing hernia repair.

Hernia repair is one of the most common surgeries in the U.S. with approximately 800,000 inguinal hernia and 350,000 ventral hernia procedures performed annually [1,2]. Hernia repair surgery can range from simple to very complex, can be performed with minimally invasive robotic/laparoscopic or open surgical techniques, and is dependent on hernia type, size, location, wound status, patient co-morbidities, and prior surgeries. Since studies have shown that mesh-based hernia repairs lead to less recurrence as compared to non-mesh or suture repairs [3], surgeons perform the majority of hernia repairs today with the use of mesh.

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The majority of simple, first-time, or very large non-infected hernia repairs are performed with permanent synthetic mesh, while biologic meshes are reserved for recurrent, complex, and at times infected hernias. Safety and long-term outcomes with mesh-based hernia repair have been variable and warrant further long-term studies.

Recently, long-term data from the Danish patient registry, has been published on outcomes after synthetic mesh and non-mesh repairs [4]. After five years of follow-up, while the rate of recurrence was lower in synthetic mesh repair group (12.3%) as compared to non-mesh repair (17.1%), the cumulative incidence of complications was 7 times higher, 5.6% as compared to 0.8% in non-mesh repair [4]. Long-term synthetic complications found in the study were bowel obstruction, bowel perforation, bleeding, chronic surgical site infections, late intra-abdominal abscess, enterocutaneous fistula, seroma, hematoma, nonhealing wound, and diagnostic surgery due to pain that was not required for patients not receiving a mesh implant.

As the healthcare market evolves, patients are requesting a bigger role in their healthcare decision making process. For example, 70-80% of patients use their cell phones to search the diagnosis that their primary care physician provided. On the internet, patients are encountering data on hernia repair techniques and reinforcement materials that is of variable quality. In addition, they are being exposed to the growing litigious environment surrounding mesh via targeted social media marketing and inorganic search engine optimization (paid SEO). The waves of litigations started with urogynecological meshes but are now expanding into the traditional hernia repair space. As awareness increases, surgeons are faced with a growing number of questions and hurdles of preconceived notions regarding both technique and reinforcement materials, some of which is accurate and some of which is questionable. As a result, surgeons are seeing an influx of patients that are asking a multitude of questions about mesh, its associated complications, and/or requesting no mesh hernia repairs. Patients exposure to mesh complication media through personal research and internet driven advertising is driving them to demand an active role in the hernia repair decision making process. We sought to better understand our patients' concerns, goals, and values through a shared decision-making model to improve patient satisfaction and decrease litigious exposure.

Shared decision-making (SDM) is a process in which clinicians and patients work together to make decisions and select tests, treatments and care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values [5]. However, best practices for shared decision-making are only now emerging in response to calls for more value-based and patient-centered healthcare. Knowledge and time limitations, coupled with little regulatory action around SDM, has kept the practice under the radar for some clinicians.

The SDM model has 3 steps [6]:

1. Introducing choice
2. Describing options, often by integrating the use of patient decision support material

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3. Helping patients explore preferences and make decisions.

This model rests on supporting a process of deliberation that leads to a decision based on informed preferences that is based on respecting 'what matters most' to patients as individuals [6]. SDM is supported by evidence from 86 randomized trials showing knowledge gain by patients, more confidence in decisions, more active patient involvement, and, in many situations, informed patients elect for more conservative treatment options [7]. Informed preferences are an optimal goal because the decisions made will be better understood, based on more accurate expectations about the negative and positive consequences [8] and more consistent with personal preferences. Studies have shown that there is a link between anxiety and wound healing, where higher anxiety leads to slower, and in some cases worse, wound healing [9]. Patients who get to participate in SDM have lower anxiety than patients that do not [10]. Getting informed consent for the procedure, not just consent, is at the heart of SDM and has been very important for the patients and providers [11]. For all these reasons we felt that SDM would not only decrease anxiety but also increase patient satisfaction and potentially outcomes as well.

With the growing demand for no mesh hernia repairs being generated by access to information and exposure to growing litigation, as well as newer "more natural" mesh materials becoming available, we chose to give our patients a choice in hernia reinforcement material for their repair. The options we elected to provide them with are a resorbable synthetic, reinforced biologic, and permanent synthetic. When discussing available options with patients, we always emphasize that the largest body of published data and in our historical experience is with the classic permanent synthetic meshes, as compared to resorbable synthetic and reinforced biologic.

A cohort of 142 patients were offered a choice in their hernia repair material in a shared decision-making process. This included all hernia patients receiving either open or minimally invasive ventral/incisional/umbilical or inguinal repair. 133 patients (93.7%) opted for a reinforced biologic material, 8 patients (5.6%) chose permanent synthetic mesh and 1 patient (.7%) chose a completely resorbable bio-synthetic mesh. Of the 133 patients that chose the reinforced biologic material, 46 (34.6%) patients had previously placed permanent synthetic mesh that was being removed for failure or other related complications, and 87 (65.4%) were having a primary repair. Of the patients receiving primary repair, 6 patients had a hernia size of 1cm or less and did not require reinforcement. 8 patients elected to have permanent synthetic mesh after a complete discussion of the options and the factors specific for their hernia. Of these, 1 (12.5%) patient chose permanent synthetic mesh based on his previously successful repair on the contralateral side using synthetic mesh. Factors contributing to the selection of permanent synthetic mesh in the remaining 7 patients were: location (flank), complexity (very weak tissues), or patient desired technique. The 1 patient that chose the resorbable bio-synthetic insisted on having no permanent foreign material. All patients were made aware of the known pros and cons of each product, including our low recurrence and complication rates

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with permanent synthetic materials and the less understood recurrence rates with the other materials. Our clinical outcomes to date have been comparable to before we implemented this SDM approach and offered the new repair material options. Based on real-time patient reported outcomes in our practice utilizing a HIPAA compliant communication application, patient satisfaction has been very high, pain medication has been reduced, and return to normal activity has been requested earlier than our prior experience.

When patients are well informed of the risks and benefits of the use of hernia repair material, they elected to have their hernia repaired with the reinforced biologic option. We believe this choice of reinforcement is due to their understanding that a non-mesh repair likely has a higher recurrence rate, their tissue is weakened, and that they could benefit from some degree of long-term tissue strengthening. Their concerns with conventional permanent synthetic mesh seem to revolve around permanent foreign body response and risk of downstream complications. Additionally, there seems to be a desire for a "more natural" alternative. In general, SDM, as has been shown in other fields of medicine, improved patient satisfaction, patient compliance, and decreased anxiety about the treatment plan. Our experience has been consistent with these findings. We believe SDM will continue to improve patient satisfaction and reduce legal exposure around this complex topic. Shared decision-making in hernia repair warrants further investigation and we plan to study it with a broader group of surgeons and their patients.

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