

AIHTA study once again finds no superiority of robot-assisted surgery for breast and abdominal procedures

The Austrian Institute for Health Technology Assessment (AIHTA) has evaluated the efficacy and safety of robot-assisted surgery (RAS) in 14 indications in the thoracic and abdominal regions. Against the backdrop of high expectations and significantly higher costs compared with laparoscopic and open surgery, the study focused on the added benefit of RAS. The conclusion was that there was no evidence for several indications and endpoints, differences in hospital stays and readmissions were not statistically significant, and the evidence on the duration of surgery was contradictory. Overall, few of the touted benefits of RAS could be demonstrated. The report now published was an update of an EUnetHTA report from 2019, when AIHTA (as LBI-HTA) already found insufficient evidence, partly because relevant outcomes were not reported or measured or did not show statistically significant differences.

Vienna, August 31st 2023 – Robot-assisted surgery (RAS) is considered a technically advanced form of laparoscopic surgery: the operation is performed in a minimally invasive way with the help of remote-controlled mechanical arms attached to the operating table. The robot acts with the highest precision, which allows it to operate in very narrow areas that would otherwise only be accessible by means of open surgery. In addition to the benefits common to minimally invasive surgery - such as lower risk of infection or shorter recovery times - RAS is expected to improve quality of life, reduce use of healthcare resources and improve clinical outcomes. However, there is no consensus or accepted standards for optimal training programs for RAS.

The AIHTA has now conducted a study to investigate how RAS in the thorax and abdomen compares to conventional - laparoscopic and open - procedures. For this purpose, the scientists evaluated twenty randomized control trials of RAS for different procedures in the thoracic, esophageal, gastrointestinal, and gallbladder/liver/spleen regions with a total of 2085 patients. The study focused on patient-relevant and safety-related outcomes (such as survival, quality of life, or complications) and resource utilization (e.g., length of hospital stay). "There is a severe lack of high-quality comparative evidence on performance evaluation of robotic-assisted surgery. In particular, endpoints that play an important role for patients, such as quality of life, satisfaction, or the time to return to work and daily activities, are hardly reported in the studies," criticizes Nicole Grössmann-Waniek, study leader and researcher at AIHTA.

High expectations, high manufacturer density, no training standards

However, the high expectations do not end with the patients: In addition to the ergonomic benefits for surgeons, the RAS is expected to create additional benefits at the organizational and clinical levels: On the one hand, the use of health care services is expected to decrease, for example through shorter length of stay, fewer readmissions and lower utilization of hospital beds. On the other hand, better clinical outcomes are expected, for example, lower blood loss, fewer transfusions and a lower overall complication rate. "While no additional staffing is required, according to the manufacturers, additional education and training of surgical staff is required. There is no consensus or accepted standards for optimal training programs for this purpose," Grössmann-Waniek explains. According to the AIHTA report, most studies used the da Vinci® Surgical System. However, 19 manufacturers currently offer robotic systems to support surgical procedures, ten of which are CE-marked products.

Evidence and cost factor

In the 2019 report update, AIHTA researchers identified studies for nine of 14 surgical procedures: namely, lobectomy, anti-reflux/fundoplication, esophagectomy, gastrectomy, colectomy, rectal resection, ventral

rectopexy, hernia repair, and hepatectomy. In contrast, no randomized control trials could be identified for Heller myotomy, bariatric surgery, small bowel resection, mediastinal surgery, and cholecystectomy. However, the relevant endpoints were either not reported, not measured, or did not show statistical significance in most studies. "In general, robotic-assisted surgery is associated with higher costs in acquisition and maintenance. Despite potential price reductions, it also has increased environmental impacts due to energy and material consumption compared with conventional laparoscopic procedures," Grössmann-Waniek pointed out. Nevertheless, RAS could be beneficial for some indications and endpoints, according to the report: For example, studies reported lower blood loss from RAS for lung lobectomies, esophagectomies, rectal resections, hepatectomies, and gastrectomies. Postoperative complications also occurred less frequently after robot-assisted gastrectomies, rectal resections, and hepatectomies. However, according to AIHTA, a general statement on the efficacy and safety of RAS is not possible. This is mainly due to the heterogeneity of the results and the lack of evidence for some endpoints. Therefore, both factors, i.e., the limited quality of evidence as well as the financial and environmental impact of RAS, should be considered when making purchasing decisions.

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