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EDITORIAL

Registries: what level of evidence do they provide?

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The last couple of years a large number of innovative surgical techniques to correct genital prolapse and/or stress incontinence have been introduced. As a result uro-gynaecologists are confronted with a new dilemma: Should they start using these promising new surgical techniques, or should they await the results from randomized controlled trials (RCT) with long-term follow-up before doing so?

It is no surprise that, together with the introduction of new surgical techniques, the use of registries for the evaluation of their outcome have gained in popularity. These registries provide a tool to gather information on short notice: Registries are easily accessible for physicians, do not need informed consent from the patient, do not demand for any additional investigations, and allow for data registration at any time that is comfortable for the doctor. Furthermore, it has been argued that, in contrast to other sources, the results from registries are more readily generalizable as the data do not depend on selection of patients or doctors but are derived from daily clinical practice. The advantage over a RCT due to larger sample sizes is that registries can provide information about rare events and complications.

However, there are important risks in the interpretation of data generated by registries.

Firstly, registries are subject to confounders. Without the accurate identification and measurement of confounders, it may be difficult to estimate the true relationship between exposure(s) and outcome(s) of interest. An important confounder concerns the patient characteristics included in the registry, as there is no control on who is included and who is not. Patients with low complication risks who underwent a straightforward procedure may be overrepresented. Whenever severe complications occur, the attending physician may be too busy with solving these problems and may simply forget to register this complicated case, or the opposite may happen whenever the physician feels that it is especially important to register cases with adverse outcomes based on the motivation to share these experiences with colleagues.

Secondly, there is no control on the quality of the data collection. Mostly, financial support to allow high-quality data collection has not been provided. As a result the reliability of documentation, e.g., amount of blood loss, estimated surgery time, pelvic organ prolapse quantification (POP-Q) score after surgery, mainly depends on the motivation of the physician and his/her team. Furthermore, the quality of data collection may be hampered by the selection of subjective outcome measures, e.g., when physicians are asked to score the encountered difficulties in performing the procedure on a 7-point Likert scale.

Thirdly, many registries have been initiated by medical companies producing surgical meshes or devices. By definition, business interests are involved in these databases. As a result, the primary outcome in these registries is not necessarily the one with the highest clinical relevance. It is imaginable that the industry sponsoring these registries has a goal to document a favorable outcome of their products. Furthermore, many clinical relevant outcome measures (e.g., patient satisfaction, treatment adherence, costs) are, in most cases, not included in a registry, as these are quite difficult to obtain.

As a consequence of the limitations of registries, it is difficult to compare the obtained results to those of prospective comparative studies. Therefore, the problem with registries is that wrong conclusions may be drawn with

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respect to both complication and success rates of innovative surgical techniques.

Because of the business interests involved, the absence of prospective data entry, the judgement of clinical outcomes by directly involved physicians, and the lack of a proper control group undergoing standard treatment, the reliability of registries as data sources should be judged with utmost care. From a scientific viewpoint, therefore, registries cannot possibly compare with data provided by randomized trials, and physicians motivated to contribute to studies hopefully decide to participate in multi-center comparative studies rather than in registries.