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On behalf of the TaTME Guidance group representing the ESCP (European Society of Coloproctology), in collaboration with ASCRS (American Society of Colon and Rectum Surgeons), ACPGBI (Association of Coloproctology of Great Britain and Ireland), ECCO (European Crohn's and Colitis Organisation), EAES (European Association of Endoscopic Surgeons), ESSO (European Society of Surgical Oncology), CSCRS (Canadian Society of Colorectal Surgery), CNSCRS (Chinese Society of Colorectal Surgery), CSLES (Chinese Society of Laparo-Endoscopic Surgery), CSSANZ (Colorectal Surgical Society of Australia and New Zealand), JSES (Japanese Society of Endoscopic Surgery), SACP (Argentinian Society of Coloproctology), SAGES (Society of American Gastrointestinal and Endoscopic Surgeons), SBCP (Brazilian Society of Coloproctology) and the Swiss-MIS (Swiss association for Minimally Invasive Surgery)

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Dear Editor,

We thank Gachabayov *et al* for their thoughts and appreciation of our recently published International Expert Consensus Guidance on TaTME [1], and the opportunity to clarify any misunderstandings regarding its purpose and methodology. Firstly, the panellists consisted of 56 internationally known and respected surgeons, experienced in managing rectal cancer not only by TaTME but also by the abdominal approaches. They have performed over 50 TaTME cases each, taught on cadaveric courses, and published literature on the technique. They were also identified and recommended by their national colorectal surgical societies. Given that the aim of the consensus was to formulate guidance specifically on the safe implementation and application of TaTME, rather than the management of rectal cancer as a whole, it is very reasonable for the panel to be composed of practicing surgeons experienced in TaTME. The number of panellists allowed us to bring together the worldwide experience of the technique, with representatives from each of the 14 international societies who also recognised and endorsed the importance of this project. Five rounds of Delphi were required to reach agreement on the statements over three years, suggesting that conformity bias was unlikely as each surgeon clearly expressed their opinion leading to many hours of discussion. The authors quote that 16% of the panellists have a conflict of interest. As stated on the consensus article and on the contrary to another misleading consideration, none of the participants have any direct conflict of interest with regards to the paper. To be open and transparent however we listed commitments with industry by individual

participants. It is not unusual, and in the current era of advancing technical innovation, for specialist senior surgeons to consult and provide direction for these companies.

Secondly, the methodology used consisted of an adapted Delphi method and focus group discussion approach, guided by an expert in guidelines methodology. Consensus was considered achieved when agreement level of >80% was reached. The authors reference a perspective on the Delphi process by Waggoner et al [2] in which the opinion of the three authors was to only include a panel size of 6 – 11 members, based on a few studies and "the lack of current research" [2]. This is in contrast to an extensive set of experiments conducted at the RAND corporation which clearly showed a positive correlation between increasing number of participants with accuracy and reliability of the responses [3]. The size of the panel in most Delphi studies is incredibly variable [2], and often reflects the research question and underlying purpose of conducting the Delphi process which may well lead to varying numbers of participants.

The guidance group acknowledged that at the present time there is no level 1 evidence on TaTME. However, published evidence is accumulating rapidly and, hence we proposed the new concept of "dynamic guidance", whereby the guidance could be updated as more evidence becomes available. Randomised controlled trials such as COLOR III [4] and ETAP-GRECCAR11 [5] have started patient recruitment but results will not be available for some time. Given the dynamic character of the statements, we also strongly advocated all societies to publish these guidance statements online for review and critical appraisal of their respective membership. Peer review by the wider colorectal community will allow further adaptation and improvement of the current statements.

We agree that "Clinical expertise in the era of evidence-based medicine and patient choice should be integrated with evidence, patients' preferences, and clinical circumstances" [6]. However, in the context of surgical innovation this is not so straight forward as a technique (and the surgeon's skill in performing it) may still be evolving and its true benefits and risks not fully known yet.

TaTME is currently in the early part of the assessment phase of the IDEAL framework for surgical innovation [7]. Despite following the IDEAL recommendations and steps closely, especially during the early development of the technique [8], the explorative phase saw a huge surge in TaTME adoption worldwide. This was largely unregulated and unstructured with variable access

to adequate training and provision of experienced proctors. Unsurprisingly, problems soon arose with concerns regarding urethral injuries [8], CO2 embolus [10] and more recently local recurrence [11,12]. It is exactly during these times of widespread discussion and concern about a technique that a consensus is needed. Although the panellists in this consensus may be viewed as being "in favour of TaTME" simply because they perform the technique, the guidance produced actually calls for caution and sets more preconditions and direction for surgeons considering adopting TaTME. By having personally faced the challenges that TaTME can bring, the panellists acknowledge that certain standards and pre-requisites are necessary in order to safely implement the technique. Pre-requisites, such as a minimum annual volume of TME cases, obtaining appropriate training and acquiring advanced surgical skills, are not achievable in every colorectal unit; thus limiting the adoption of TaTME. Furthermore, by setting these standards through the consensus process, self-licensing is more likely to be prevented.

Finally, we feel that the statement "the concept of expert canters is outdated" is incorrect. Expert centres for novel and challenging techniques are vitally important for their safe introduction. Parallels have already been seen with minimally invasive oesophagectomy [13] and endovascular aortic aneurysm repair [14]. The definition of 'expert centre' in our consensus contained three components: 1) Centre specifications; 2) Surgeon expertise; 3) Centre performance/outcomes. The latter two categories actually achieved agreement levels of 97.9% and 91.7%, respectively. Only 'centre specifications' obtained 62.5% agreement despite lengthy discussions and a further Delphi round. The discussion points regarding this component highlighted the diversity in surgical practice and resource availability around the globe. However, the panellists agreed that complex high-risk cases should not be performed in low volume units sporadically by inexperienced surgeons. Regular exercise of an activity or skill is the way to become proficient in it, hence the importance of securing a high case volume in a well-resourced department.

In conclusion, TaTME captured the colorectal community's attention, due to perceived advantages, and enthusiasm has led to widespread uncontrolled adoption. This occurred despite the lack of high-level evidence of its equivalence to conventional TME approaches. The International Expert Consensus Guidance aims to promote a more cautious and considered roadmap for the introduction of this new technique into clinical practice. With strong

collaboration, sharing of experiences, high-quality research and regular review of available evidence, surgical innovation can continue to evolve and allow us to provide better patient care.

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