

Final evaluation report convention complex surgery oesophagus – recommendations formulated by the Audit Belgian Esophageal Surgery

October 2023

To Ms Marleen Louagie, Head of Medical Directorate at RIZIV/INAMI

During the extraordinary meeting of 11 October 2023, the Audit for Belgian Esophageal Surgery (ABES) group, as the scientific organization for esophageal cancer surgery in Belgium, representing all experts centers currently performing esophageal resections in Belgium, discussed extensively the results of the convention for complex esophageal surgery (1 July 2019-30 June 2022) including the questions formulated during the last steering committee on the convention for complex surgery of 20 September 2023.

The ABES explicitly wants to thank the team of the Cancer Registry for their tremendous work and the close collaboration with the ABES during the past years.

The ABES wants to make the following statements that are unanimously supported by all centers involved:

1: The ABES does believe that the above described convention has been successful in improving results for patients treated by esophagectomy for cancer, although the ABES realizes that the 30-day mortality as well as the 90-day mortality were not significantly improved ($p=0.087$ and $p=0.076$ respectively) compared to the T0 measurement (esophageal resections in Belgium between 2015 and 2018).

The reasons therefore are:

- **A 33% reduction in adjusted 30-day mortality** (from 4.2% in the T0 measurement to 2.8% during the convention, OR 0.671 95%CI [0.42-1.06]) **and a 25% reduction in adjusted 90-day mortality** (from 9.5% in the T0 measurement to 7.1% during the convention, OR 0.765 95%CI [0.57-1.03]) **is undoubtedly a clinically relevant reduction**. Before the start of the convention, clear end points, such as a minimal reduction in mortality, were never defined nor calculated. Moreover, **it is statistically impossible to reach a significance level of $p < 0.05$ based on the current numbers**: T0 measurement included 1584 (T0: 2015-2018) esophageal resections and the convention included 1184 (2019-2022) esophageal resections. When a randomized study would be designed to achieve a 33% reduction in 30-day mortality as primary outcome (e.g. from 4.2% to 2.8% as now), **it would require a sample size of 5408 interventions to achieve statistical significance** ($\alpha=0.05$ and power=0.8). This is a good reason to further extend the convention and within a few more years, the ABES is more than convinced that this convention will prove its successfulness.
- **T0 results and convention results are not perfectly comparable**. Two examples are that in the T0 certain characteristics cannot be checked to compare (because there was no registration yet) and early stage cancers (like T1 cancers) were preferentially surgically treated during the T0, whereas they were preferentially endoscopically treated during the convention. Stage migration, with inherent risk of complications could potentially be another explanation for the mortality numbers.

- **During the second year of the convention, adjusted 30-day mortality as well as the adjusted 90-day mortality were higher than expected** (respectively 4% and 10.9%). **Internal audit within the ABES** after the second year of the convention undoubtedly **revealed at least at partial effect of the COVID-pandemic**. During the third year of the convention, the adjusted 30-day mortality and adjusted 90-day mortality were markedly better (respectively 1.2 % and 4.1%) and therefore more within the expectations for the next years.

The current results of the convention – not only mortality data (2.0 and 4.5% respectively), but also morbidity data, such as anastomotic leakage rate and length of stay – are within the range of large international data sets and therefore reassuring¹.

And besides the improved results for the patients, **the convention has also created new cooperation agreements and solid protocols within the centers and** consortia to ensure that the care for these patients is as optimal as possible and without delays.

There is currently a close cooperation **between the expert centers**, where information is exchanged and analyzed and knowledge is shared.

The convention also gave rise to the creation of research projects aiming to improving quality by joint scientific projects, in close collaboration with the cancer registry and the RIZIV/INAMI.

2: The ABES, as the scientific organization for esophageal cancer surgery in Belgium, representing all experts centers currently performing esophageal resections in Belgium, is not the correct institution to decide whether volume criteria defined before the convention, should be strictly applied or not.

It is up to the RIZIV-INAMI to decide which centers will be allowed to a potentially renewed convention or not.

3: The ABES is strongly recommending to communicate the results of the convention to the broad public for the following reasons:

- There is a thorough prospective registration of patients, therapy choices, complications, morbidity and mortality. **Such a complete complication registration is unprecedented in Belgium**. A dataset that is analyzed extensively and meticulously, monitored, discussed and mediated where necessary by the members of the Belgian Cancer Register, must therefore be shared with the public.
- **The ABES deeply regrets that quickly drawn conclusions** based on a report that is still in the assessment phase (by national and international experts) **are released** by individuals or union members in such a short-sighted manner. In addition, some statements and the conclusions are completely wrong. **Conclusions should be correctly drawn and the results should be well explained to the colleagues as well as to the public.**

¹ Kuppusamy et al. Ann Surg 2022 **Evaluation of International Contemporary Operative Outcomes and Management Trends Associated With Esophagectomy: A 4-Year Study of >6000 Patients Using ECCG Definitions and the Online Esodata Database.** doi: 10.1097/SLA.0000000000004309.

- **It is the scientific responsibility and duty of the ABES to publicly react on the incorrect information that was spread in the press concerning the convention.** The ABES will do that very soon.
- Article 6.11 in the **RIZIV-INAMI contract** signed by all centres **mentions** - amongst others - **the peer-reviewed publication of data.**

4: The ABES has the following vision on the future of this or the next convention for complex esophageal surgery:

- **Volume alone will in the future not suffice as a criterium to allow a center to the convention or not.** Outcome and therefore quality criteria will be at least as important future criteria to judge the activity of a center.
- **The future convention should include all esophageal cancer patients, irrespective of the clinical stage or type of treatment.** It should therefore include all medical specialties taking care of these patients, preferentially in consortia linked to an expert center.
- **Outcome registration and follow up of these patients should be more rigorous** with registration of all complications (not only grade Clavien/Dindo grade 3b or higher) and follow up longer than 3 months.
Patient reported outcome measures (PROMS) and patients reported experience measures (PREMS) would be of added value as well as quality of life measurements.
- Clear definitions (for example on the pathologic report of the resection specimen, but also on the classification of an anastomotic leak or a chyle leak should be made. Teaching moments on correct registration are therefore crucial.
The ABES will take the initiative to create correct definitions during one of its next meetings with peer teaching on the correct registration process of these definitions by clinical case scenarios.
- Although current data sets of the convention are probably unprecedented in Belgium, only mortality is a hard end point. **All other data must be audited in order to have a correct clinical and scientific meaning and to improve future data sets.** Since there still has yet been no form of auditing suggested by the RIZIV/INAMI, **the ABES will engage to agree on a peer-to-peer audit system between centers.**

To conclude, the ABES strongly believes in the future goal of the convention to improve the care of all esophageal cancer patients. Therefore the ABES also believes that the results of the first 3 years of convention are a big step in the right direction and that these results need to be published and explained to the public.

The ABES wants to stress that the multidisciplinary care for esophageal cancer patients can only further improve if all esophageal cancer patients with all medical specialties taking care of them, are included in the future convention. There is room for further improvement by better registration, including more data such as PROMS and PREMS, research collaborations, etc, but this is only possible with the necessary funding.

The ABES is willing to take the lead in defining future outcome parameters, improving registration and peer-to-peer audits, but it also wants to remind the RIZIV/INAMI that a mortality reduction of 25% to 33% has never been reached for a certain disease without any cost...