

Completeness and selection bias of a Belgian multidisciplinary, registration-based study on the Effectiveness and quality of Endometrial Cancer Treatment (EFFECT)

KU LEUVEN

Kom op tegen Kanker

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EFFECT
A study on quality and effectiveness of endometrial cancer treatment in Belgium

Belgian Cancer Registry

Introduction

In Belgium, large inter-hospital variations exist in the clinical care of corpus uteri cancer^a. Therefore, with the aim of obtaining more uniformity and quality in the management of corpus uteri cancer in Belgium, the EFFECT-project has prospectively collected detailed information on the real-world clinical care offered to 4063 Belgian women diagnosed with this cancer between 2012 and 2016^b. However, as this data was collected on a voluntary basis, a selection bias may be present. This study therefore aimed to assess the completeness and potential selection bias of the EFFECT-database.

Methods & Materials

- Five databases were deterministically coupled by use of the patient's national social security number as unique identifier: (a) the Belgian Cancer Registry (BCR) database; (b) the InterMutualistic Agency (IMA) database; (c) the Crossroads Bank for Social Security (CBSS); (d) the EFFECT-database; and (e) a database provided by the Federal Public Service of Health (FPSH)^c.
- Participation bias was assessed by comparing characteristics (FPSH data) of hospitals participating and not participating in EFFECT. A hospital's volume expresses the number of patients treated per year, and was categorized into low-, medium- and high-volume (i.e., <10, 10-19 and ≥20/year, respectively).
- Registration bias was assessed by comparing characteristics (BCR, IMA and CBSS data) of patients registered and not registered for EFFECT.
- Uni- and multivariable logistic regression was applied. All statistical tests were two-sided and p-values below 0.05 were considered statistically significant.

Results

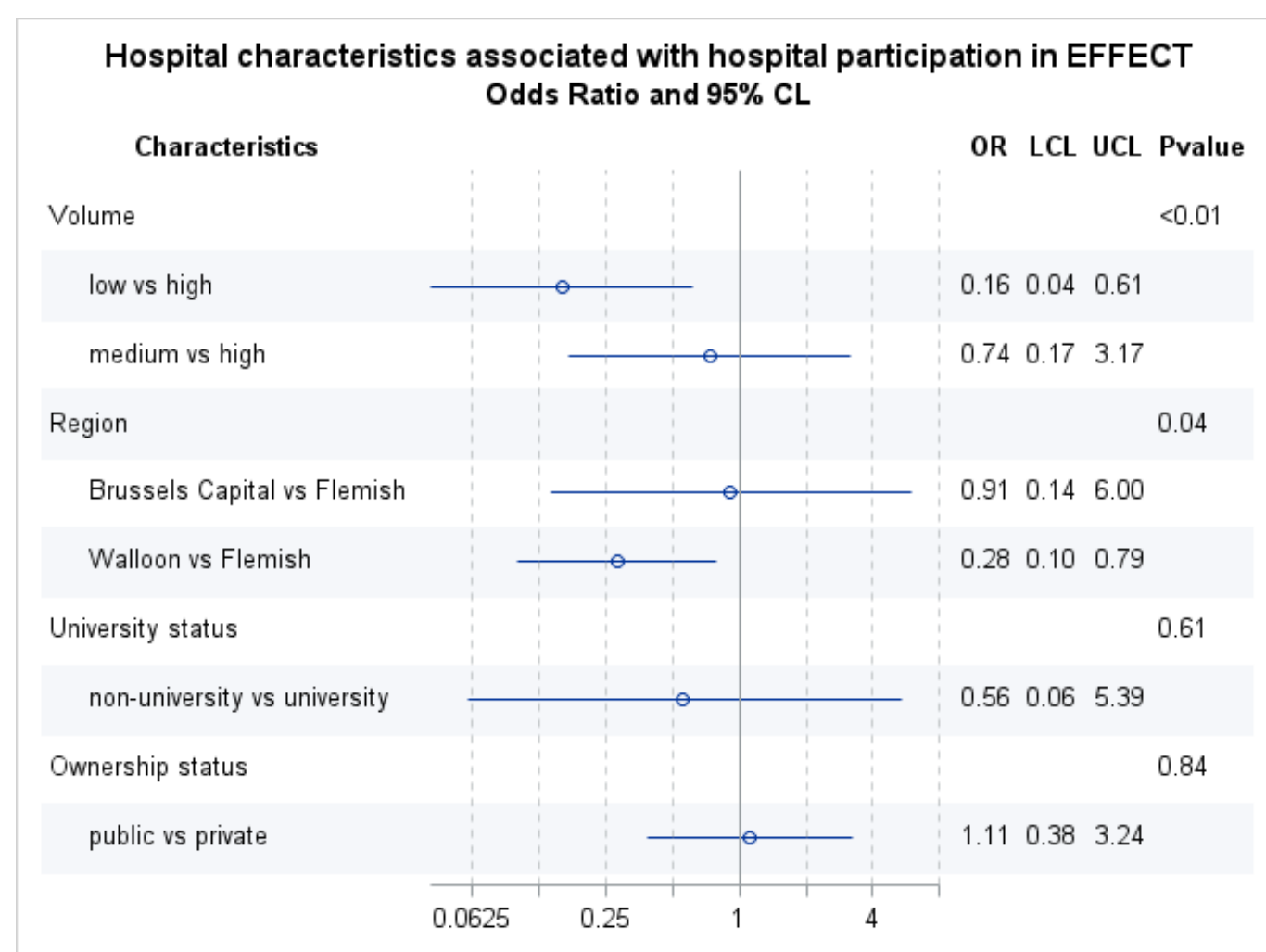


Figure 1. Results from multiple logistic regression: odds ratio's (ORs) and 95% confidence limits (CLs) for hospital participation in EFFECT. LCL=lower confidence limit; UCL=upper confidence limit.

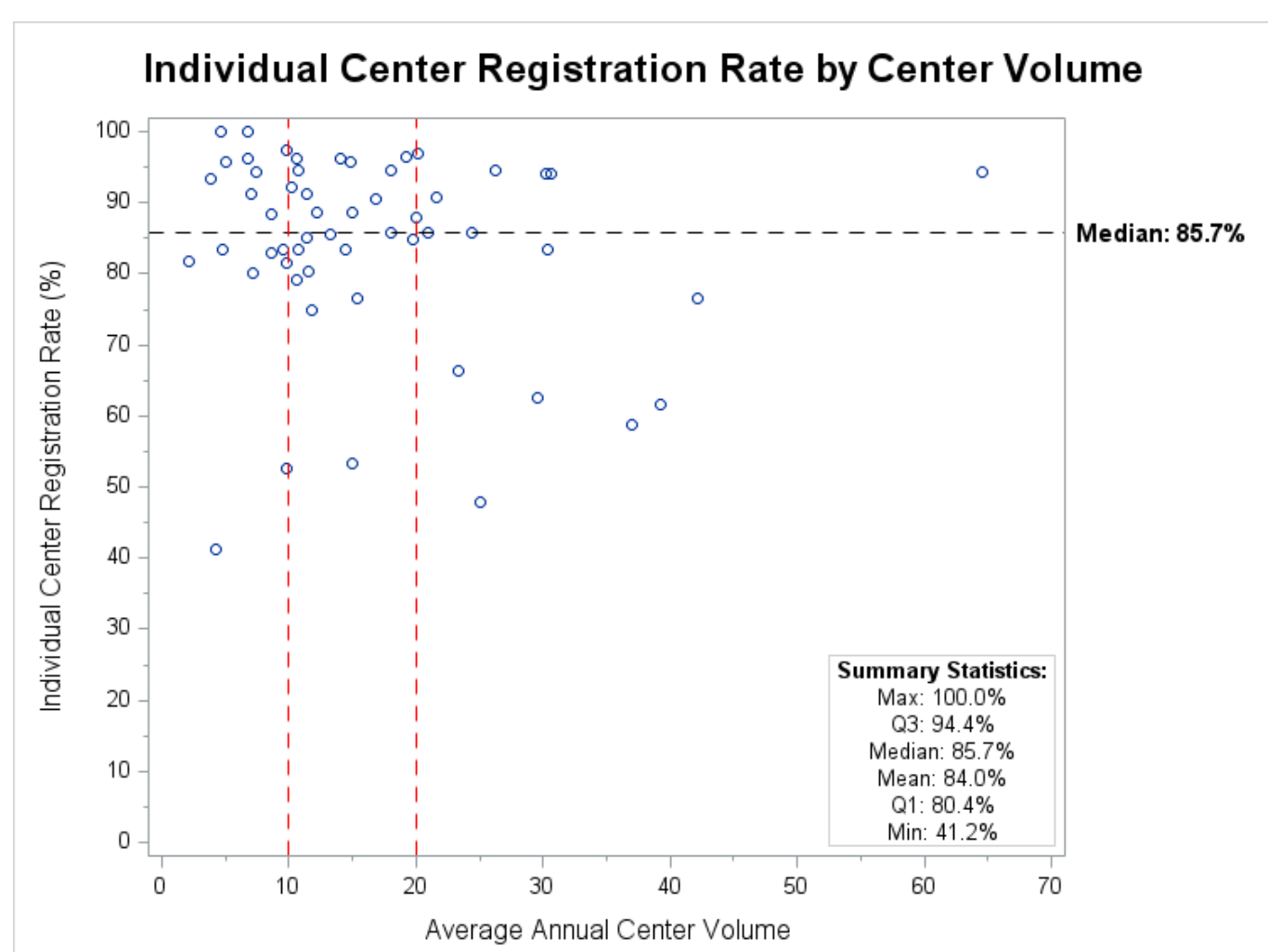


Figure 2. Patient registration rate for the 55 EFFECT- participating centers individually. Each dot represents one individual participating hospital. The vertical, dashed lines represent the cut-off values used for categorizing centers into low-, medium- and high-volume.

The EFFECT-database covers 56.1% (4063/7239) of Belgian women diagnosed with primary corpus uteri cancer between 2012 and 2016.

Participation of hospitals was found to be incomplete and biased:

- Of all Belgian hospitals treating corpus uteri cancer in the period 2012-2016, 54.5% (55/101) did participate in EFFECT.
- Both low-volume centers and centers from the Walloon region were less likely to participate and are therefore underrepresented in EFFECT (Figure 1).

Patient registration by participating centers was found to be incomplete and biased:

- Participating hospitals registered a median of 85.7% (IQR=80.4%-94.4%; range =41.2%-100.0%) of their patients (Figure 2).
- Patients with a less favorable risk profile, with missing data, that did not undergo curative surgery, and that were not discussed in a multidisciplinary tumor board (MDT) were less likely to be registered (Figure 3).

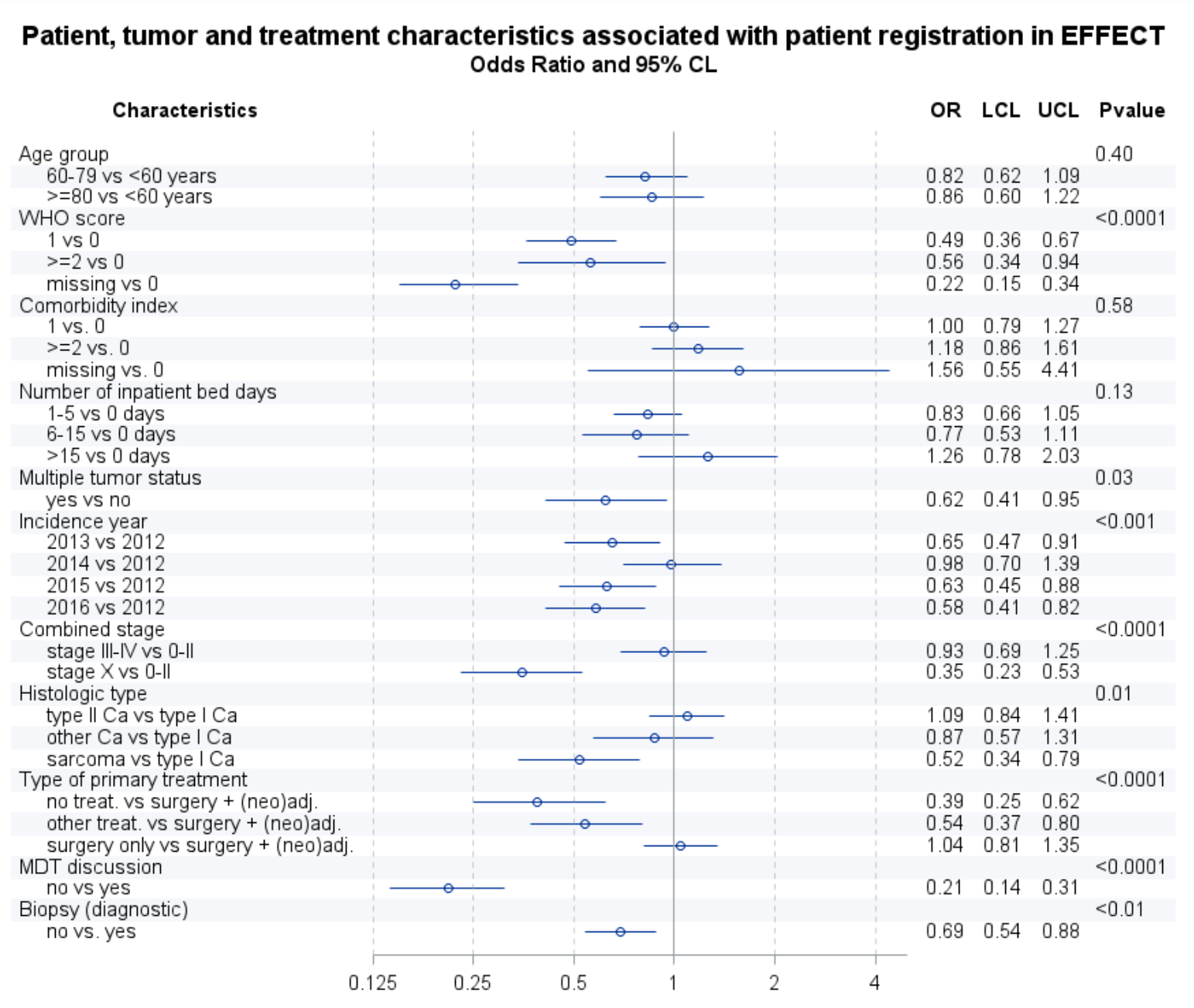


Figure 3. Results from multiple logistic regression: odds ratio's (ORs) and 95% confidence limits (CLs) for patient registration in EFFECT. LCL= lower confidence limit; UCL=upper confidence limit; WHO=World Health Organization.

Discussion

- These findings confirm previous data that voluntary registration of healthcare data by Belgian hospitals results in both participation and registration bias^d.
- Despite the overall positive attitude towards the project, a lack of resources may have been a major reason why not to participate for many of the hospitals, particularly for those of low volume (e.g., a lack of funding, time, personnel and/or technical support)^{e, f}.
- The following mechanism may explain the observed registration bias: the trigger for participation may have come from surgeons in many of the participating hospitals, therefore preferring to include patients that underwent surgical resection^d. However, this requires further investigation.

Conclusions

- The EFFECT-database is biased due to its voluntary nature. However, having assessed and characterized this selection bias, we will still be able to perform a valid and accurate analysis and interpretation of EFFECT-data.
- This study demonstrates the importance of characterizing the selection bias that is potentially present in any registration-based study that voluntarily collects information that is not otherwise routinely collected.

References

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