

SUPPLEMENT 2

Validation of variables in SNRUBC in stage T1 tumors diagnosed 2008-2009

Background: To correctly interpret data from the diagnosis form in the Swedish National Registry of Urinary Bladder Cancer (SNRUBC) when reporting data and in scientific research, we aimed to validate the data for selected variables related to diagnosis for all clinically stage T1 (cT1) tumours during the years 2008 and 2009.

Method: All patients registered as cT1 in the SNRUBC in the were included in the study (n=1044) [1]. Two specially trained nurses with broad experience of registration in the SNRUBC and other national population-based urological registries were employed to perform a second professional registration of the entire study population by doing a second review of all available patient charts. Care was taken to avoid that one nurse performed both the primary registration and the second registration of the same patient. All registered variables were thus registered once more without knowledge of the results from of the primary registration. Variables reregistered were date of referral to a urologic consultation and a transurethral resection (TUR) of the tumour. Tumour characteristics such as tumour grade according to WHO 1999 classification and clinical TNM category (TNM 2010) and primary treatment were also reregistered. The validation registration was also completed with information about T category of the second-look resection.

Results: The time from referral to TUR were similar in the primary registered and validated registrations as illustrated in **Figure 1**. There was similarly a high concordance between primary registration and validated registration with respect to cT stage (**Figure 2**), where 92% of the patients were registered as cT1 based on the information from patient charts. Of the patients with other than cT1 at validation, 4% had a lower clinical T stage, 2% had a higher stage, 1% were TX, and 3 % had missing data making validation impossible. We found concordance between registered data of grade as compared to the clinical journals for 82% of the G1 tumours, 89% for G2, and 92% for G3 (**Table 1**).

Concordance between primary registration and validation of clinical nodal (cN) stage and clinical metastasis (cM) stage were lower (**Table 2 and 3**). Of patients registered in SNRUBC with N0/NX, 96% had the same information whereas among the few patients with N+ (n=10) only 30% had the same information during validation with information from available patient charts. Similar pattern was found for cM, with very high concordance, 96%, among patients with M0/MX, but only 27% among the few patients registered as M1 in the SNRUBC (n=15).

Conclusion: In the SNRUBC primary registration of cT1 urinary bladder cancer, the concordance with clinical journals were high, However, improved registration of cN and cM are necessary. Continuous validation projects and programmes to detect and correct weaknesses in the registration process is important.

Figure 1. Density estimation of time from referral to transurethral resection (TUR) of the bladder tumour. Comparison of data in the diagnosis registration form in the SNRUBC and patient charts (validation data). Higher the curve means higher number of patients with that value.

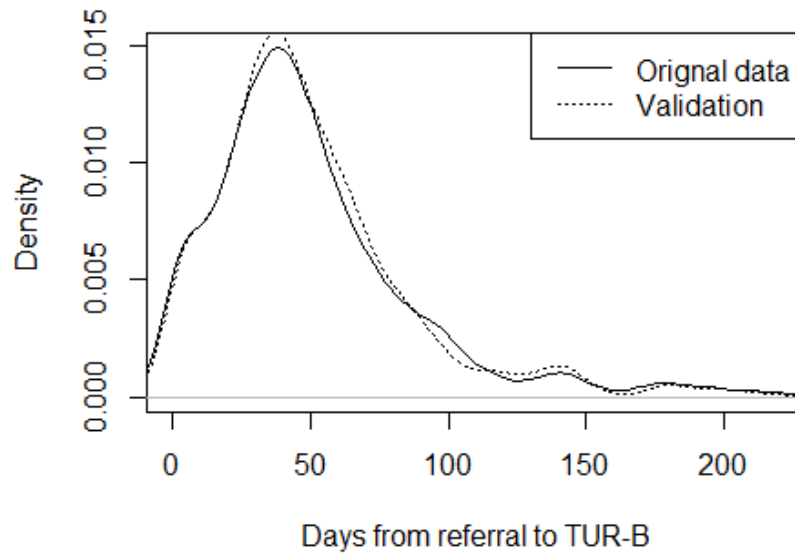


Figure 2. Concordance of clinical T stage of all patients registered as clinically stage T1 in the validation study. Data from patient charts were used as validation data.

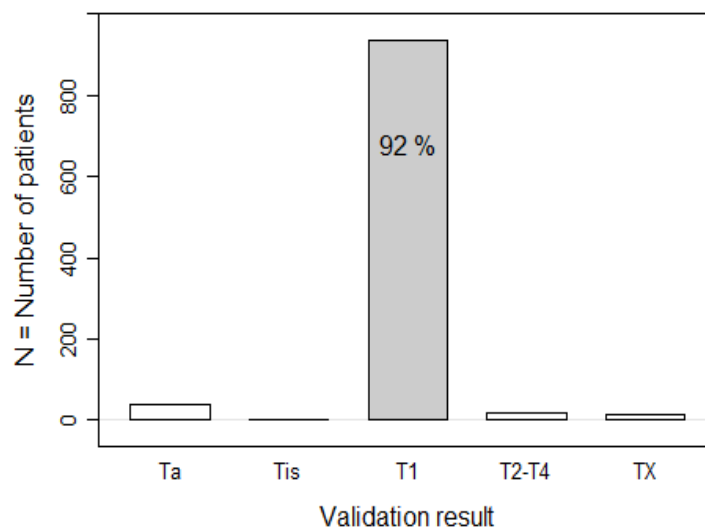


Table 1. Concordance between grade registered in the diagnosis form in the SNRUBC for all clinical stage T1 patients diagnosed 2008-2009 as compared to data obtained during validation.

| SNRUBC register | Patient charts | | | | | |
|-----------------|----------------|------------|-------------|-------------|----------|-----------|
| | | G1 | G2 | G3 | GX | Missing |
| G1 | | 31 (81.6%) | 3 (7.9%) | 3 (7.9%) | | 1 (2.6%) |
| G2 | | 2 (0.5%) | 379 (89.0%) | 31 (7.3%) | 2 (0.5%) | 12 (2.8%) |
| G3 | | | 21 (3.7%) | 519 (91.7%) | 7 (1.2%) | 19 (3.4%) |
| GX | | | | 2 (66.7%) | | 1 (33.3%) |
| Missing | | | 2 (18.2%) | 2 (18.2%) | 1 (9.1%) | 6 (54.5%) |

Table 2. Concordance between clinical node (cN) stage registered in the diagnosis form in the SNRUBC for all clinical stage T1 patients 2008-2009 as compared to data obtained during validation.

| SNRUBC register | Patient charts | | | |
|-----------------|----------------|-------------|-----------|-----------|
| | | NO/NX | N+ | Missing |
| NO/NX | | 989 (95.7%) | 12 (1.2%) | 32 (3.1%) |
| N+ | | 7 (70.0%) | 3 (30.0%) | |
| Missing | | 1 (100%) | | |

Table 3. Concordance between clinical metastasis (cM) stage registered in the diagnosis form in the SNRUBC for all clinical stage T1 patients 2008-2009 as compared to data obtained during validation

| SNRUBC register | Patient charts | | | |
|-----------------|----------------|-------------|-----------|-----------|
| | | M0/MX | M1 | Missing |
| M0/MX | | 986 (95.9%) | 9 (1.0%) | 33 (3.2%) |
| M1 | | 10 (66.7%) | 4 (26.7%) | 1 (6.7%) |
| Missing | | 1 (100%) | | |

References

1. Patschan, O., et al., *Second-look resection for primary stage T1 bladder cancer: a population-based study*. Scand J Urol, 2017. **51**(4): p. 301-307.