

## EFFECT OF COMPLETE BLADDER NECK PRESERVATION (CBNP) ON CONTINENCE AND QOL - A RANDOMISED CONTROLLED TRIAL

### Hypothesis / aims of study

To investigate the effect of strict and complete bladder neck preservation (cBNP) on continence and quality on life (QOL) after radical prostatectomy (RP) for cancer of the prostate.

### Study design, materials and methods

A randomised controlled prospective study between 2009 and August 2011 was initiated to verify the effect of cBNP on continence. 192 patients were recruited, randomised to cBNP or non- cBNP and followed up for 12 months. The cBNP-Group comprised of only patients who had a strict preservation such that the proximal urethra could later be anatomised to the distal urethra. Data was collected on patient age at operation, period of catheterisation, prostate volume, preoperative PSA-Value, Gleason score, resection margin, tumour pathology and lymph node status. At 3, 6 and 12 months 24h-pad test, pad use, IQOL-score and oncological outcome were evaluated. Only patients with no pad usage were deemed continent.

### Results

Final results of the complete collective will be available at the beginning of August 2011 and can be presented in the congress. Preliminary results of this study show significantly higher early continence rates in the cBNP-Group. At 6 weeks, 12 weeks and 3 months 17.6 vs. 56.3% (p=0.033), 55.9 vs. 81% (p=0.12) and 72.2% vs. 88% (p=0.04). There is no significant difference in continence at 6 months. No significant difference was found as far as QOL and oncological outcome are concerned.

### Concluding message

Preliminary results show that cBNP as performed in our institution has a significant effect on early continence. This though seems to have no significant effect on the quality of life. Final results of the complete collective will be presented at the meeting.

<b>Specify source of funding or grant</b>	<b>No funding or grant</b>
<b>Is this a clinical trial?</b>	<b>Yes</b>
<b>Is this study registered in a public clinical trials registry?</b>	<b>No</b>
<b>Is this a Randomised Controlled Trial (RCT)?</b>	<b>Yes</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Ethikkommission der Medizinischen Fakultät Heidelberg <a href="http://www.medizinische-fakultaet-hd.uni-heidelberg.de/Ethikkommission.106025.0.html?&amp;FS=0&amp;L=de">http://www.medizinische-fakultaet-hd.uni-heidelberg.de/Ethikkommission.106025.0.html?&amp;FS=0&amp;L=de</a></b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>