

EVALUATION OF VOIDING PATTERN IN MEN WITH INFRAVESICAL OBSTRUCTION USING A NEW INK16 TOOL

Hypothesis / aims of study

INK16 (index of contractility) is a math expression for bothering infravesical obstruction developed for obstruction severity assessment and its changes after commencing a patient on alphablocker therapy. Its unit is one Newton, where **m** is replaced by specific urine gravity of voided volume (Vtotal) multiplied by voiding acceleration in **mL/s²**. The comparison of men, women without obstruction and patients with clearly obstructive enlarged prostate prior and after at least three months of treatment gave distinctive and valid results, which could be used in evaluation of medical treatment for BPH. The INK16 seems to be suitable tool for comparing various drugs for BPH therapy among themselves.

Study design, materials and methods

Four test groups of patients were created, young men without obstruction (code=1), women (code=2), men with obstructive BPH prior therapy (code=3) and men on therapy for at least 3 months (code=4). Evaluated parameters of UFM were: A-point of max. acceleration of micturition, B-voided volume in Qmax, C-point of Qmax, and D-point of micturition accomplishment, Ttotal and Vtotal, Graph 1. The alphablocker used was original tamsulosin ® at 0.4 mg daily. The results of all groups were tested with parametrical Aspin-Welch modification of T-test and non-parametrical Wilcoxon Rank-Sum test of Medians, both on p<0.05. The plotted relation was as follows:

$$\text{INK16} = \frac{V_{\text{total}}}{1000} * \text{SQRT}\left(\left(\text{tg } \alpha * \frac{Q_{\text{max}}}{T_{\text{inc}}}\right) * \left(\frac{V_{\text{inc}} * 100}{V_{\text{total}}}\right)\right),$$

where No. 16 stands for normal distribution of interrelated values in parametrical and non-parametrical statistics (while other tested plots had not the normal distribution).

Results

Graph No. 1

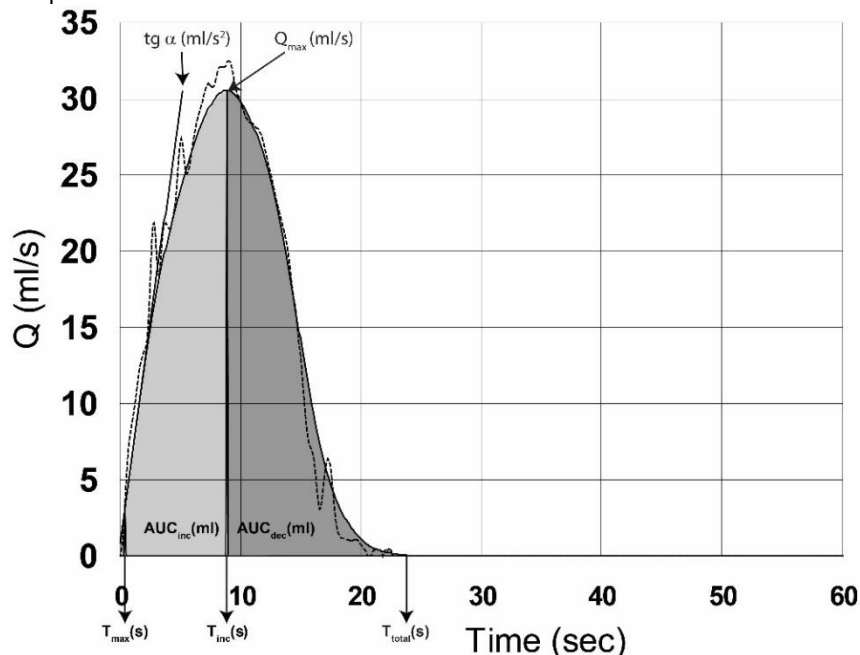


Table 1 - Descriptive statistics

| | Age | | | | BMI | Point A-tg alpha | INK16 |
|--------|-----|-------|----------|--------|--------|------------------|---------------|
| | No. | Mean | SD | Median | Median | Median | Median |
| Code=1 | 54 | 25.22 | 5.916611 | 24 | 25 | 4.305 | 6.775 |
| Code=2 | 26 | 40.65 | 5.418061 | 41 | 26,85 | 6.6 | 11.825 |
| Code=3 | 32 | 56.46 | 5.724787 | 58 | 28 | 2.35 | 2.53 |
| Code=4 | 32 | 56.46 | 5.724787 | 58 | 28 | 3.8 | 4.075 |

Table 2 - Comparative studies

| | INK16/Ag e | INK16/BM l | INK16/tg alpha | INK16/AUCin c | INK16/Ttota l | tg alpha/Qmax | Qmax/Ttota l | tg alpha/Vtotal |
|------------|---------------|---------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------------|
| Code= 1 | N/S | N/S | P<0,0000 | p = 0.7765 | p = 0.0908 | p = 0.0146 | p = 0.0036 | p = 0.1739 |
| Code= 2 | N/S | N/S | P<0,0000 | p = 0.9957 | p = 0.0695 | p = 0.0268 | P = 0.0012 | p = 0.0083 |
| Code= 3 | N/S | N/S | P<0,0000 | p = 0.8654 | p = 0.2879 | p = 0.0938 | P = 0.0271 | p = 0.1935 |
| Code= 4 | N/S | N/S | P<0,0000 | p = 0.0621 | p = 0.0513 | p = 0.0249 | p = 0.0012 | p = 0.0810 |

Table 3 - Comparison of obstruction on INK16 basis

| | Count No. | A-W T-test | Wilcoxon test |
|-------------------|-----------|-----------------|-----------------|
| Code 1 vs. Code 2 | 54/26 | 0.009266 | 0.013300 |
| Code 1 vs. Code 3 | 54/32 | 0.000000 | 0.000009 |
| Code 1 vs. Code 4 | 54/32 | 0.054044 | 0.049864 |
| Code 3 vs. Code 4 | 32/32 | 0.003604 | 0.002812 |

Interpretation of results

Index of contractility INK16 is neither dependent on age nor BMI. It is highly dependent on acceleration of voiding stream and when on desobstructive medication it is only shy of significance in increasing volume and micturition time in treated men. Acceleration to maximum flow and relation of Qmax to total micturition time is very similar between the non-prostate owing women and treated men on alphablockers. While the significant difference was found between unobstructive men and women, the significant difference was not found between unobstructive men and treated men pointing to the reliable efficacy of the treatment. In pre-treatment and treated groups, there were significant differences on the INK16 basis. Thus the efficacy of alphablockers could be measured among themselves on the basis of comparing INK16 of treated men and those of young controls and pre-treatment values of men with symptomatic BPH. All the measurement are simple as only UFM curves in ASCII mode are employed for inter and intracohort comparison.

Concluding message

Correct and scientifically based comparison of obstructed patients on pharmacological therapy could bring a reliable rationale to the patient-oriented tailoring of appropriate medical therapy to an individual patient.

Disclosures

Funding: N/A **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics not Req'd:** the design of the study was not focused on new drug development and the study was completely non-invasive. All minded data were from routinely sampled clinical common records. **Helsinki:** Yes **Informed Consent:** Yes