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A SYSTEMATIC REVIEW OF EFFICACY OF TAMSULOSIN AS THE FIRST-LINE TREATMENT FOR LOWER URINARY TRACT SYMPTOMS(LUTS) ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA(BPH) IN JAPAN

Hypothesis / aims of study

This is pilot study of global systematic review of tamsulosin by evidence-based medicine.
We focused on Japan, have many high evidence level randomized controlled trials(RCT) according to the various and rich experience of tamsulosin.
There were some previous studies of systematic review of tamsulosin. But these studies have two crucial limitations. One is that outcome measurement is separated as International prostate symptom score(IPSS) and Boyarsky symptom score. Second is that target references to studies included in review articles are 10 years ago at least.
Therefore, this systematic review was conducted with one outcome measurement trials as IPSS; common evaluating tool for LUTS/BPH. Also, we selected the latest target reference until 2012.

Study design, materials and methods

Trials were searched in computerized general and specialized databases (MEDLINE, EMBASE, Cochrane Library), by researchers. Study characteristics were assessed and data extraction was performed independently by two reviewers. Extracted data was reviewed by the principal reviewer and discrepancies resolved by discussion.
The primary outcome was change in urological symptoms measured by IPSS. Statistical software Rev Man5.0 was used for meta-analysis and risk of bias of studies, recommended by Cochrane Collaboration. As a measure of overall methodological study quality we assessed the quality of concealment of treatment allocation according to commercially available software as GRADEpro.
Search strategy. A MEDLINE search strategy with certain MeSH headings, including prostatic hyperplasia, lower urinary tract symptoms, and tamsulosin. EMBASE, the Cochrane Library, and the prostatic diseases and urologic malignancies group specialized registry were also searched in a similar fashion. Reference lists of identified trials and reviews were searched for additional trials. There were no language, no publish time restrictions.
Inclusion criteria is that RCTs of using tamsulosin for LUTS associated with BPH in male. Exclusion criteria are that abstract only, open label, cross over study, non outcome measurement(IPSS), single arm(not control), review, systematic review, meta-analysis articles.

Results

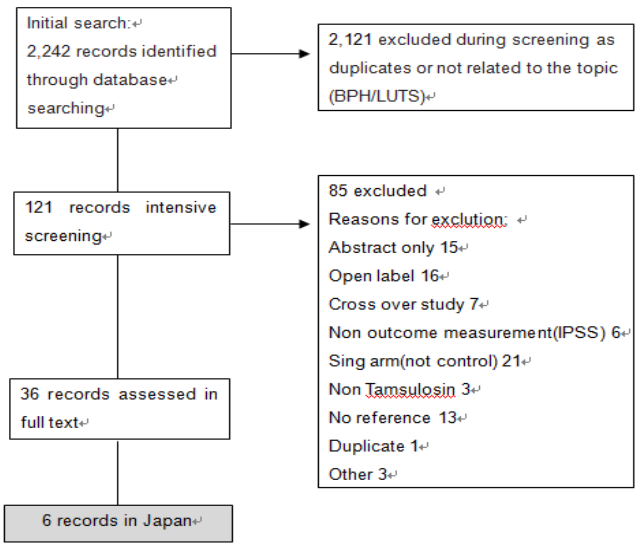

Figure 1. Flow chart of the screening of this study.

We first found 2,242 studies which met inclusion criteria. After reading the title and summary, finally there left 6 by exclusion criteria (Fig 1).
A total of 439 men were randomized this study. Study duration ranged from 4 to 24 weeks. All 6 active-controlled trials were not described allocation concealment. Only 1 study is conducted in double-blind (Kawabe 2006) (Table 1).

Interpretation of results

Table 1. Randomized trials of Tamsulosin for BPH/LUTS in Japan

References	Drug (dosage/control)	Subjects/ Withdrawals	Subject Description	Study Duration	Double-blind	Allocation Concealment Qualtity
Okada et al	Tamsulosin(0.2 mg qd) / Terazosin(2mg qd)	61/4	Japanese men (mean age 65.7 years) with IPSS of>13 and a maximum urinary flow rate (Qmax) of <12 mL/s	4 Wks	No	Unclear
Gotoh et al	Tamsulosin(0.2 mg qd) / Naftopidil(25 mg qd for 2	185/41	Japanese men (mean age 68.5 years) with IPSS of>8 and a	12 Wks	No	Unclear

	Wks follwed by 50mg qd for 10 Wks)		maximum urinary flow rate (Qmax) of <15 mL/s, voided volume of ≥ 150 mL, and a prostate volume of ≥ 20 mL			
Yokoyama et al	Tamsulosin(0.2 mg qd) / Naftopidil(50 mg qd) / Silodosin(4 mg bid)	136/0	Japanese men (mean age 71.5 years) with IPSS of>8	12 Wks	No	Unclear
Masumori et al	Tamsulosin(0.2 mg qd) / Naftopidil(50 mg qd)	95/22	Japanese men (median age 64 years) with IPSS of>8, PVR ≤ 200 mL	12 Wks	No	Unclear
Kawabe et al	Tamsulosin(0.2 mg qd) / Silodosin(4 mg bid) / Placebo	457/1	Japanese men (mean age 65.6 years) with IPSS of>8, an associated quality-of-life (QoL) score of ≥ 3, and a maximum urinary flow rate (Qmax) of <15 mL/s, PVR ≤ 100 mL, voided volume of ≥ 100 mL and a prostate volume of ≥ 20 mL	12 Wks	Yes	Unclear
Kurita et al	Tamsulosin(0.2 mg qd) / Allylestrenol(50 mg qd)	128/7	Japanese men (mean age 65.6 years) with IPSS of>13, a maximum urinary flow rate (Qmax) of <15 mL/s	24 Wks	No	Unclear

The mean change of IPSS improvement from baseline for tamsulosin was -7.23 (95% CI -7.68, -6.79). Heterogeneity test showed *P*<0.00001, so the null hypothesis that all six studies were homogeneous was not rejected. Thus, we adopted fixed-effects model (Fig 2).For the evaluating bias about each trials, we used Cochrane Risk of bias assessment tool, all of trials showed randomization, complete outcome data. For the evaluation overall methodologic study quality, this systematic review study showed High level by GRADEpro.

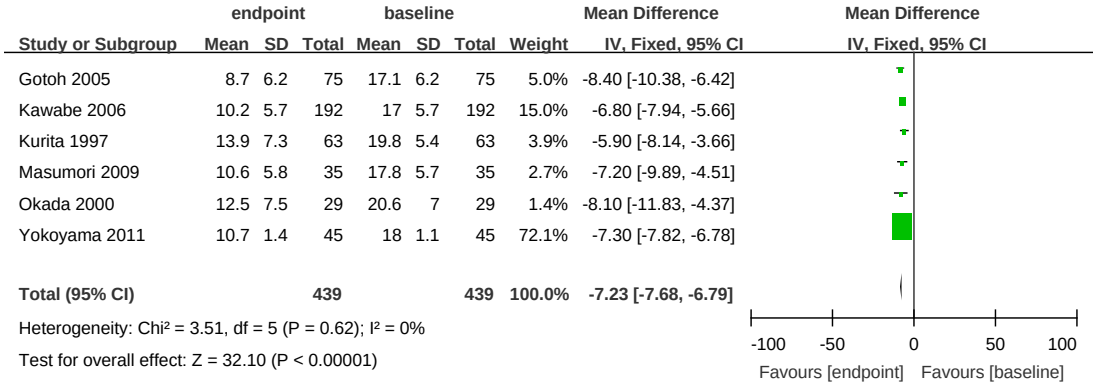

Fig 2. Forest plot of Tamsulosin in Japan studies.

Concluding message

A systematic review aims to provide an exhaustive summary of literature relevant to a research question. And systematic reviews of high-quality randomized controlled trials are crucial to evidence-based medicine.

This systematic review study indicates that tamsulosin provides improvement in LUTS/BPH. And also at present study has a limitation of focus on Japanese RCTs. But if we conduct global systematic review of tamsulosin for LUTS/BPH consistently, it is helpful our understanding about improvement and adverse event rate, differences of race in each countries.

References

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Disclosures

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