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RESEARCH ARTICLE

ELECTRICAL STIMULATION, PELVIC FLOOR MUSCLE EXERCISES, AND URINARY INCONTINENCE IN POST-PROSTATECTOMY PATIENTS: CONTROLLED RANDOMIZED DOUBLE-BLIND EXPERIMENT

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ABSTRACT

Objectives: To verify if the electrical stimulation (ES) associated with the training of the pelvic floor muscles (PFM) as conservative treatment reduces urinary incontinence (UI) in prostatectomy men.

Patients and methods: Patients with UI were randomized into two groups: PFM Exercises (PFME group) and electrical stimulation exercises more PFM (EE + EPFM group), with a weekly frequency from twice to 20 sessions.

Results: Five of the 20 patients EPFM group and 10 patients in the 15 EE group + EPFM become continents, or no longer needed daily use protectors contain urine lost. Thus, the absolute risk of remaining in EPFM incontinent group was 0.75, whereas in the EE + EPFM group was 0.33. Electrical stimulation reduced the absolute risk of being incontinent at 42%. Relatively, this risk has been reduced from 56% (95% CI = 0.21 to 0.95).

Conclusions: The data obtained in this study showed that the combination of electrostimulation the years of MAPs significantly reduced urinary incontinence in patients undergoing radical prostatectomy.

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INTRODUCTION

The increased frequency of prostate cancer in recent years is worrying medical science and men in general. There are two distinct processes in relation to the prostate, the first is the benign growth called hyperplasia, which affects almost 90% of men after 40 years and the second is prostate cancer, which comes with or without the benign growth and almost always present in men after 50 years (Srougi, 1998). Prostate cancer is the most common tumor in Brazilian men, having been estimated about 61,200 new cases in 2016, according to the National Cancer Institute (INCA), accounting in 2013 for 13,772 deaths (INCR, 2016). Radical prostatectomy is the primary treatment of prostate carcinoma and although highly effective in the elimination of disease recurrence and increase survival, these benefits are generally overcome by impaired quality of life, mainly related to treatment side effects, such as incontinence urinary (UI) and erectile dysfunction (Perchon *et al*., 2008). The post-radical prostatectomy UI is a complication difficult to treat and has a profound negative impact on the daily life of the individual, caused by iatrogenic damage of urinary sphincters (Craig and Comiter, 2010). In the treatment of benign disease, this complication occurs in less than 1% of cases. In radical prostatectomy, the incidence ranges from 2% to 87% (Lima *et al*., 2006). The International Continence Society (ICS) recommends the exercises of the pelvic floor muscles (MAPs) for the conservative treatment of UI as first option, because it is a technique that involves low cost and risk, and proven efficacy (Figueiredo *et al*., 2008 and Abrams *et al*., 2009). The use of electrical stimulation as conservative treatment for UI does not have enough studies to demonstrate its effectiveness, but this technique is used to provide the passive contraction of the pelvic floor muscles (MAPs), contributing to the awareness of the contraction of muscles in patients who have difficulty in identifying the same (Moreira *et al*., 2001). Thus, treatment with electrical stimulation can increase the success of exercises for the pelvic muscles in patients with urinary incontinence after radical

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prostatectomy (Moore *et al*., 1999). With this, the aim of this study was to determine whether the use of electrical stimulation associated with the exercise of MAPs as conservative treatment reduces urinary incontinence in prostatectomy men.

MATERIALS AND METHODS

This randomized controlled trial (RCT) was drawn from the recommendations CONSORT Statement (Schulz *et al*., 2010), duly registered with the Clinical Trials under the NCT02073721 number, which can be accessed by: http://www.clinicaltrials.gov

Delineation

This study was conducted from August / 2013 to December / 2013 in Pelvic Physical Therapy Clinic of the Federal Hospital of the State Server (HFSE), located in the municipality of Rio de Janeiro / RJ, Brazil. The study was an experiment with active control, randomized, double-blind, parallel intervention. Patients after referral of HFSE Urology passed by a blind screening done by a specialist physiotherapist in Pelvic Physical Therapy, and then met the eligibility criteria were randomly allocated into two groups: Group exercises MAPs (EMAPs), which is the active control and the group electrostimulation more exercises MAPs (EE + EMAPs). The weekly frequency was twice, and the number of sessions that were needed to recover the urinary continence, not exceeding 20. The success criteria for achieving urinary continence was the use of no daily disposable protector. The physiotherapist specialist in Pelvic Physical Therapy who applied interventions, did the pre- and post UI. The evaluation was done by another specialist physiotherapist who underwent a two-week standardization of assessment procedures training. Data analysis was blinded.

Sample

Ofthatexperimentparticipated patients with urinary incontinence by sphincter deficiency with clinical diagnosis given by the doctor, resulting in a radical retropubic prostatectomy surgery, referred by urologists of HFSE; with the maximum time after surgery up to six months; who used 2 to 5 disposable pads per day. Patients with symptoms of urinary tract infection; Symptoms of obstruction of the lower urinary tract; anal fistula; metal implant in the body; transurethral resection of the prostate; prior radiotherapy; and that did not perform the proposed treatment were excluded. The patients were informed about the study and signed an informed consent. The authors received formal authorization from the head of the Outpatient Clinic of Urology / HFSE for the implementation of this study. This study met the standards of CNS466 Resolution / 12 and was approved by the Research Ethics Committee of the University Gama Filho, with the protocol number 06436712. 0.0000.5287.

Sample size

The sample size was estimated by the G Power 3.0.10 software. The following data were entered: Test family: z tests; Statistical test: Proportions:Differencebetween two independent proportions; Type of Power analysis: A priori compute required size sample - Given α, power and effect size; Input parameters: Tail (s) = one; Proportion p2 = 0.5411; Proportion p1 = 0.14; α err prob = 0:05; Power (1 - prob β err) = 0.80; allocation ration N2 / N1 = 1.20. How to output the parameters G Power generated critical z = - 1.65; sample size group 1 = 15; sample size group 2 = 19; Total sample size = 34; current power = 0.81.

Randomization

For the random allocation of patients to one of EMAPs and EE + EMAPs groups were used functions = IF (RAND () <0.500001, 1, 2) Microsoft Office Excel® 2005 generated a list of 100 random numbers " 1 or 2". According to the patient order entry in the study, it was awarded the random number "1" or "2" generated by EXCEL. If "1" the patient went to the EMAPs group, "2" the patient went to the EE + EMAPs group.

Intervention for EMAPs group

Execution of exercises supervised MAPs was performed by patients following the verbal Physiotherapist statement that called for the implementation of diaphragmatic inspiration along with the relaxation of MAPs, then exhale slowly contract the MAPs, like hold urine, since there is an agonist-antagonist relationship between respiratory diaphragm and the perineum (Laycock, 1994; Barbosa *et al*., 2009). The patient in the lateral decubitus position, knees and hips flexed held two series of 5 maximal contractions of MAPs at intervals of 6 seconds between them in order to work the phasic fibers. For this, the physiotherapist with properly gloved hands made a digital touch the anal canal and with the other hand placed on the abdomen made control of concomitant contraction of this muscle with MAPs, with the aim of learning and automation by the patient. Also in this position, the patient underwent 3 sets of 8 contractions supported by 4/2 of MAPs at intervals of 4 seconds between them in order to work the tonic fibers. Seated in the chair with your feet flat on the floor and in the standing position, leaning against the wall, with your feet parallel and semi-flexed knees, they were repeated exercises to work the tonic fibers, as described above. Duration 20 minutes protocol.

Intervention for the EE group + EMAPs

Patients underwent electrostimulation with endoanal electrode (Dualpex 961 - Quark®) in the lateral decubitus position with knees and hips flexed. The parameters used were frequency 65 Hz, pulse width of 500 uS, biphasic current intensity according to the tolerance level reported by the patient, perineal stimulus time of 4 seconds, standby time of 8 seconds for 20 minutes. All patients received the verbal command Physiotherapist for contracted MAPs during electrical stimulation and relax at the electric home until the end of the session. Two minutes immediately after stimulation, these patients were subjected to years of MAPs, the same exercises carried out by the MAPs EMAPs group (active control). total duration of 40 minutes.

Outcomes

It was considered as the primary outcome urinary incontinence, which was measured before the intervention and after 20 treatment sessions or immediately after patient discharge.

Urinary incontinence

The patients were submitted to an interview about urinary symptoms, amounts of disposable pads used per day loss of urine on exertion, associated pathologies. Was asked the patient about the number of disposable guards used per day on the first visit, asking the same to stay tuned to disposable protectors

used the next day to confirm the next service this information. The success criteria for achieving continence was the use of any daily disposable protective.

Blinding

They were blinded evaluator screening, the evaluator of the primary endpoint and statistical analyst.

Data analysis

The results were presented as mean values and standard deviation. The hypothesis that electrical stimulation associated with the exercise of MAPs could reduce urinary incontinence patients was evaluated by the relative risk of being incontinent. It was established as success criteria to become continent, the use of any disposable protective.

Table 1. Characteristics of the sample

Group	Age (year old)	Time after surgery (months)	disposable protectors	PSA pre (ng/ml)	PSA post (ng/ml)	Risk Rating (cancer)		
						low risk	risk intermediate	high risk
PFMEs (n=20)	65,6 ± 6,4	3,2 ± 2,1	3,1 ± 1,0	14,8 ± 12,1	0,6 ±1,5	9 (45%)	9 (45%)	2 (10%)
ES + PFMEs (n=15)	65,1 ± 8,5	2,7 ± 1,3	2,7 ± 0,7	11,8 ± 8,8	0,1 ± 0,1	7 (46%)	8 (53%)	0 (00%)
	t = 0,19; P = 0,85	t = 0,77; P = 0,45	t = 1,45; P = 0,16	t = 0,79; P = 0,44	t = 1,43; P = 0,16	P = 0,95	P = 0,64	P = 0,28

PFMEs = Pelvic floor muscle exercises
ES + PFMEs = Electrical stimulation combined with pelvic floor muscle exercises
PSA = prostate specific antigen

Table 2. Of risk of urinary incontinence (criterion continence = zero pads / day) of groups PFMEs e ES + PFMEs

Treatment	Urinary Incontinence									
	Yes	No	RA	RRA	RR	RRR	NNT	IC 95	% n	% n %
ES + PFMEs	5	33	10	67	0,33	0,42	0,44	0,56	2	0,21 a 0,95
PFMEs	15	75		5	25	0,75				
	21			14						

RA - absolute risk; RRA - absolute risk reduction, RR - relativ risk; RRR - relative risk reduction, NNT - number needed to treat, CI - confidence interval

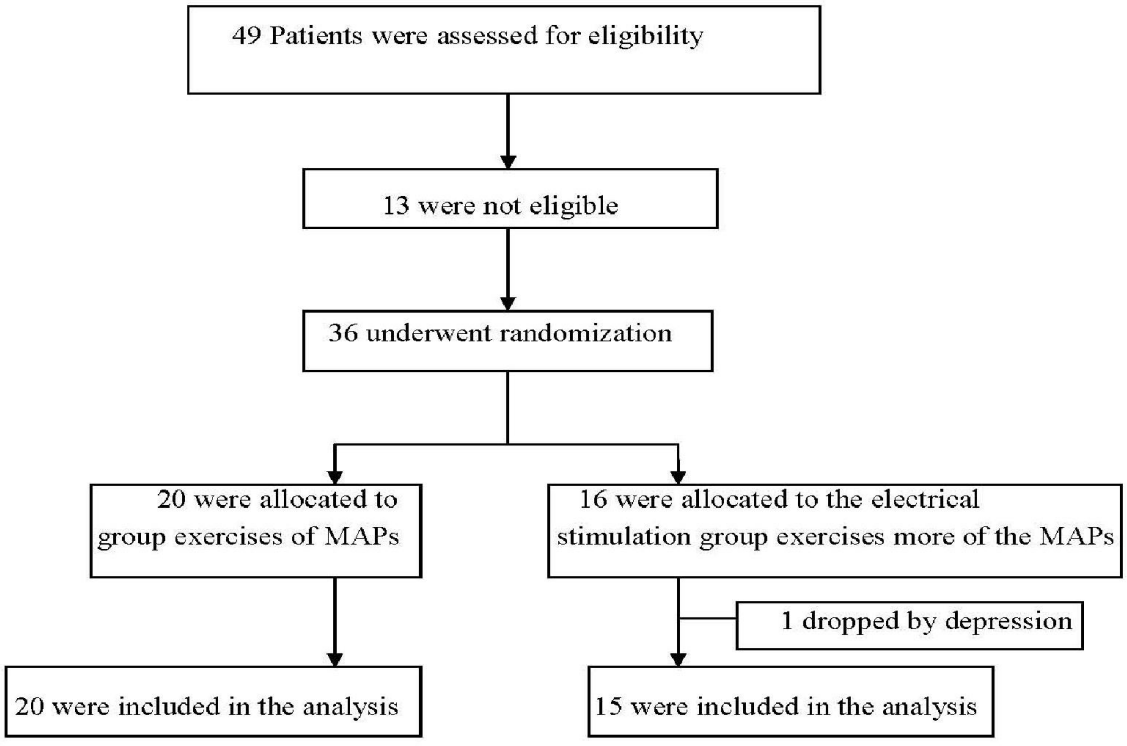

Figure 1. Flowchart

RESULTS

Figure 1 below shows the flow of the 49 patients was assessed for eligibility for the study. Thirteen patients did not meet the eligibility criteria and a total of 36 patients were randomized: 20 to the group that performed exercises MAPs and 16 for the group that underwent electrostimulation more exercises MAPs. One of the participants belonged to the electrostimulation group more exercises MAPs gave up because he was deep depression. The study was completed with 35 patients who received the planned treatment and were analyzed for the primary and secondary outcomes. Patients were referred by urologists, continuously, for physical therapy at the end of the month July and monitoring of the same was carried out between August 2013 and December 2013. The study was completed in December 2013 by reaching the number of patients required for this study, obtained by the sample calculation. The characteristics of these patients are presented in Table 1. Of the 20 patients EMAPs group, 15 remained with IU, four classified low risk nine with intermediate risk and two high risk of cancer, while the 15 patients in the EE + EMAPs group, five remained with IU, two with low risk rating and three with intermediate risk cancer classification. Eight patients had less than 20 sessions and become continents. Five were EMAPs (25%) group, all with low risk rating, with amount of 10 sessions to 16, while three were EE + EMAPs group (20%), two classified as low risk and a classified at intermediate risk with number of sessions of 6 to 10. The risk of urinary incontinence and EMAPs ES + EMAPs groups it is shown in Table 2.

DISCUSSION

The proportions of patients in whom urinary incontinence in both groups was different from the proportions reported for the estimation of the sample size. However, the post hoc test using the proportions 0.75 0.33 found in this study, with n = 20 and n = 15 for an α error of 0.05, showed a power of 0.82, above dauele estimated in the calculation of the sample, indicating a good probability of a correct decision. The random allocation of patients to EMAPs groups and EE + EMAPs along with the inclusion criteria amount of daily protectors 2-5 has two homogeneous groups in terms of age characteristics, operating time, amount of daily protectors, PSA pre- surgical, post-surgical PSA (P> 0.16) and cancer risk classification (P> 0.28), variables that could cause confounding in the study results, especially the pre-surgical PSA and cancer risk rating which showed the complexity of cancer and the resulting surgery (Table 1). Five of the 20 patients EMAPs group and 10 patients in the 15 EE group + EMAPs become continents, or no longer needed daily use protectors contain urine lost. Thus, the absolute risk of remaining in EMAPs incontinent group was 0.75, whereas in the EE + EMAPs group was 0.33. As the years of MAPs were common to both groups, it can be deduced that electrostimulation reduced the absolute risk of being incontinent at 42%. Relatively, this risk has been reduced from 56% (95% CI = 0.21 to 0.95). The combination of electrical stimulation with the absolute risk reduction of remaining incontinent 42% can be explained because the UI after radical prostatectomy surgery, is due to the anatomical lesions, which make the bladder neck least conducive to maintaining urinary continence thus generating a greater demand of the external urethral sphincter (Kakihara *et al*., 2007).

The urinary continence depends on the integrity of the internal and external sphincters, beyond the urethral and prostatic membranous segments. In turn, the external sphincter depends on the proper functioning of its striated muscle fibers (Zatsiorsky, 1999). In this study we used the electrostimulation to 65Hz with active-assisted contraction to reduce incontinence, which according to the literature, allows the predominant recruitment of fast fibers, which are located in the superficial points, where the electric current reaches more efficiently. This will only happen with voluntary contraction if the training was between 70% and 90% of the maximum load, activating all the slow fibers and most of the fast fibers (Robinson and Mackler, 2010; Fleck and Kraemer, 1997). Electrical stimulation was an additional method of MAPs strength training, which increased not only the maximum force stimulated but also the volunteer force, speed of motion and muscle strength (Abrams *et al*., 2009). The reduction in the absolute and relative risk in staying with the UI showed that the combination of electrostimulation with the exercise of MAPs reduced urinary incontinence in these patients. This result can be strengthened by comparison of the eight patients who became continent with less than 20 sessions: Patients who underwent electrical stimulation associated made 6 to 10 sessions, far less than the 10 to 16 sessions held by those who did only the exercise of MAPs.

Some authors have studied an additional effect of electrical stimulation to the exercise of MAPs on urinary incontinence in prostatectomy post found contradictory results to the present study. Moore *et al*[9] compared a group that received written guidance from nurses on exercises MAPs with a group that performed exercises MAPs under the supervision of a physiotherapist and another group that performed the same exercises of MAPs added to electrostimulation. They found no significant differences between groups. Moore *et al*. 1999 used the test pad 24 hours to determine the patients' urinary continence. However, as the pad test 24 hours can not be controlled by the researcher but the patient does not seem to be a reliable test. This seems to be true, because their level of evidence is 3 and grade of recommendation C (Wagner *et al*., 1996). Kakihara *et al* also conducted a study to see if electrostimulation potencializava exercises of home MAPs: compared a group who performed the exercises with other household MAPs group that performed the same exercises of MAPs home plus electrostimulation. After 12 months of treatment at a frequency of once a week both groups decreased significantly the amount of lost urine measured by the test pad 1 hour and the amount of used disposable pads, but there was no significant difference between groups. However, the groups were not very homogeneous at baseline for loss of urine: the group who performed the exercises of the home MAPs began the study with a urine loss equal to 9.0 ± 8.1 g, while the group who performed the same exercises of MAPs home plus three months of electrostimulation began the study with 28.0 ± 33.8 grams (three times). Observing the standard deviations of both groups, one of them is almost the mean value and the other is greater than the average, which shows substantial heterogeneity within each group. Unlike Moore *et al*. (1999) and Kakihara *et al*. (2007) the present study showed that the combination of electrical stimulation to the exercise of MAPs reduced urinary incontinence. The absolute risk reduction of urinary incontinence was 42% for those patients who have associated electrostimulation the years of MAPs. Probably the success achieved in this study was that: The criterion of urinary continence was the use of any daily protector; The

groups were initially homogeneous; Patients were randomly allocated to the groups; Evaluation and outcome of statistical analysis were blind; All patients received outpatient treatment supervised by physical therapists with experience and training in rehabilitation of the pelvic floor: After the study, the power did not change, remaining at 0.80. The UI has a major impact on health and quality of life of the individual (Aslan *et al*., 2003; Aslan *et al*., 2003). The treatment can not cure it, but improve it, preventing complications and contributing positively in their daily life (Aslan *et al*., 2003). Physical therapy performed was the significant decrease in the risk of UI. A strong point of this study was its external validity. Surgeries radical prostatectomy was performed by the medical team, the biopsy tests were performed by pathologists, evaluation and treatment of patients with urinary incontinence were performed by physical therapists Physiotherapy Service, all professionals assigned HFSE. In short, the research was conducted within the hospital environment, giving this study large external validity. Other professionals in clinics and hospitals to replicate the evaluation procedures and treatment for patients with the same clinical presentation of this study will achieve similar results to those found. The study had limitations as the achievements of surgery radical prostatectomy by different surgeons in the same medical team and the biopsy by different pathologists of HFSE. In order to reduce the consequences of these limitations, this study controlled the characteristics of the sample as shown in Table 1. It is suggested that further studies can control the limitations presented and compare different frequencies of electrical stimulation.

Conclusion

The data obtained in this study showed that the combination of electrostimulation the years of MAPs significantly reduced urinary incontinence in patients undergoing radical prostatectomy.

REFERENCES

Abrams P, Cardoso L, Khoury S, Wein A. Incontinence: Recommendations of the International Scientific Committee. 4nd ed. Paris: *Health Publication*, 2009. p. 1781-1784.

Abrams P, Cardoso L, Khoury S, Wein A. Incontinence: Recommendations of the International Scientific Committee. 4nd ed. Paris: Health Publication 2009. p. 623.

Aslan E, Beji NK, Coskun A, Yalcin O. An assessment of the importance of pad testing in stress urinary incontinence and the effects of incontinence on the life quality of women. *Int Urogynecol J Pelvic Floor Dysfunct*. 2003 Nov; 14 (5): 316-9.

Barbosa PB, Franco MM, Souza FO, Antônio FI, Montezuma T, Ferreira CHJ. Comparison between measurements obtained with three different perineometers. *Clinics*. 2009, 64 : 527-533.

Brasil. Ministério da Saúde. Instituto Nacional de Câncer. Estimativa 2016: incidência de câncer no Brasil / Instituto Nacional de Câncer. – Rio de Janeiro. INCA, 2016. p. Disponível,em:http://www2.inca.gov.br/wps/wcm/connect/tiposdecancer/site/home/prostata/definicao

Craig V. Comiter. Male incontinence surgery in the 21st century: past, present, and future. *Current Opinion in Urology* 2010,20:302-308.

Figueiredo EM, Lara JO, Cruz MC, Quintão DMG, Monteiro MVC. Perfil sociodemográfico e clínico de usuárias de serviço de fisioterapia uroginecológica da rede pública. *Rev Bras Fisioter*. 2008;12(2): 136-42.

Fleck, S. J.; Kraemer, W. J. Designing resistance training programs. Human Kinetics, 1997.

Freitas, E. V. et al. *Tratado de geriatria e gerontologia.*Rio de Janeiro: Guanabara Koogan,2002.

Kakihara CT, Sens YAS, Ferreira U. Efeito do treinamento funcional do assoalho pélvico associado ou não à eletroestimulação na incontinência urinária após prostatectomia radical. *Rev. Bras. Fisioter*. Vol.11 no.6 São Carlos Nov./Dec. 2007.

Laycock J. Clinical evaluation of the pelvic floor In: Pelvic floor reeducation. London: Springer Verlang; 1994. p. 42-8.

Lima CLM, Vaz FP, Müller V. Incontinência Urinária Pós-Prostatectomia: Tratamento. Projeto Diretrizes-Associação Médica Brasileira e Conselho Federal de Medicina, 2006.

Moore KN, Griffiths D, Hughton A. Urinary incontinence after radical prostatectomy: A randomized controlled trial comparing pelvic muscle exercises with or without electrical stimulation. *BJU Int*. 1999;83(1):57-65.

Moreira, E. C. H.; Yasuda, E. K.; Kimura, F. R. Tratamento cirúrgico e conservador da incontinência urinária de esforço. Fisioterapia em Movimento. Curitiba,v.13, n° 02, p. 9-13, outubro 2000 / março 2001.

Overgard M, Angelsen A, Lydersen S, Morkved S. Does physiotherapist-guided pelvic floor muscle training reduce urinary incontinence after radical prostatectomy? A randomized controlled trial. *Eur Urol*. 2008; 54: 438-48.

Perchon FGL, Palma CRP, Magna LA, Dambros M. Terapia grupal de comportamiento mejora la calidad de vida en hombres post prostatectomía radical. *Actas Urol Esp*. 2008; 32(7):686-690.

Robinson, A J, Mackler, L S. Eletrofisiologia clínica. 3. ed., Porto Alegre: Artmed, 2010.

Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Medicine*. 2010, 8:18.

Srougi, M. 2005. Câncer de próstata: uma opinião médica. Urologia on line [periódico na Internet]. 1998 Out-Dez [citado em Set. 2(5):[cerca de 3p.]. Disponível em: http://www.unifesp.br/dcir/urologia/uroline/ed1098/tela.htm.

Wagner TH, Patrick DL, Bavendam TG, Martin ML, Buesching DP. Quality of life of persons with urinary incontinence: development of a new measure. *Urology*. 1996 Jan; 47 (1): 67-71

Zatsiorsky, V. M. Ciência e prática do treinamento de força. São Paulo: Phorte, 1999.

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