

Holmium Laser Enucleation of the Prostate With Virtual Basket Mode: Faster and Better Control on Bleeding

Giorgio Bozzini (✉ gioboz@yahoo.it)

Dept. of Urology, ASST Valle Olona, Busto Arsizio, Italy Via Arnaldo da Brescia, 21052, Busto Arsizio (VA)
<https://orcid.org/0000-0001-6274-314X>

Matteo Maltagliati

Ospedale di Busto Arsizio

Umberto Besana

Ospedale di Busto Arsizio

Lorenzo Berti

Ospedale di Busto Arsizio

Alberto Calori

Ospedale di Busto Arsizio

Maria Chiara Sighinolfi

Azienda Ospedaliero-Universitaria di Modena

Salvatore Micali

Azienda Ospedaliero-Universitaria di Modena

Jean Baptiste Roche

Clinique Saint Augustin

Ali Gozen

SLK-Kliniken Heilbronn GmbH

Alexander Mueller

Spital Limmattal

Dimitry Pushkar

Moscow State Medical-Stomatological University

Evangelos Liatsikos

University of Patras

Marco Boldini

Clinica Sant'Anna

Carlo Buizza

Ospedale di Busto Arsizio

Bernardo Rocco

Azienda Ospedaliero-Universitaria di Modena

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Abstract

BACKGROUND:

To compare clinical intra and early postoperative outcomes between conventional Holmium laser enucleation of the prostate (HoLEP) and Holmium laser enucleation of the prostate with Virtual Basket tool (VB-HoLEP) to treat benign prostatic hyperplasia (BPH).

METHODS:

This prospective randomized study enrolled consecutive patients with BPH to HoLEP (n = 100) or VB-HoLEP (n = 100). We evaluated all patients preoperatively with particular attention to catheterization time, operative time, blood loss, irrigation volume and hospital stay. We evaluated also the patients at 3, 6 and 12 months after surgery with the use of maximum flow rate (Qmax), postvoid residual urine volume (PVR) and International Prostate Symptom Score (IPSS).

RESULTS:

We didn't see significant difference in preoperative parameters between patients in each study arm. Compared with HoLEP, VB-HoLEP resulted in less hemoglobin decrease (2.54 vs 1.12 g/dL, P = .003) and had a more rapid operative time (57.33±29.71 vs 42.99±18.51 minutes, P = 0.04). HoLEP and VB-HoLEP had same catheterization time (2.2 vs 1.9 days, P = 0.45), irrigation volume (33.3 vs 31.7 L, P = 0.69), and hospital stay (2.8 vs 2.7 days, P = 0.21). During the follow-up of subsequent 12 months, we didn't demonstrate a significant difference in IPSS, Qmax, PVR, and QOLS.

CONCLUSION:

HoLEP and VB-HoLEP both are efficient a safe procedure for relieving lower urinary tract symptoms. VB-HoLEP was statistically superior to HoLEP in blood loss and to allow a faster procedure. However, procedures did not differ significantly in catheterization time, hospital stay, operation time and irrigation volume. No differences were demonstrated in QOLF, IPSS, Qmax and PVR through the post-surgery 12 months of follow-up.

TRIAL REGISTRATION: Current Controlled Trials ISRCTN72879639; date of registration: June 25th, 2015. Retrospectively registered.

Background

Benign prostate hyperplasia (BPH), with consequent lower urinary tract symptoms (LUTS), is one of the most common diseases for patients. Many surgical treatment are available to handle BPH refractory to pharmacological therapy [1]. Transurethral resection of the prostate (TURP) remains the gold standard surgical treatment for prostates with a total volume in between 30 and 80 ml. Open prostatectomy (OP) is used for enlarged glands (> 80 ml) [2]. Nowadays, laser enucleation of the prostate is gradually replacing

these old techniques because of outcomes, the advantage of decreased bleeding complications and the safety. Laser procedures are indicated for the treatment of prostate > 80 ml and they can be considered as an alternative to TURP for prostates with a total volume between 30 and 80 ml [1, 3].

The BPH laser instrumentation is composed by many technologies and techniques [4]. HoLEP was introduced around 20 years ago by Fraundorfer and Gilling [5] and, since then, a lot of studies has demonstrated that HoLEP offers a better outcome than classical technique for BPH, in terms of duration of hospital stay, postoperative catheterization time, and intraoperative and postoperative bleeding [6]. During this procedure, Surgeons, with a resectoscope, have to cut and detach adenoma from the prostate surgical capsule with a blunt dissection, and with the holmium laser they have to make an accurate coagulation. In the matter of the holmium laser emission output, 80–120 W is generally used with settings of 1,8–2.5 J and 20–50 Hz.

Nowadays, Ho:YAG laser is used also for stone lithotripsy, during which, the impact of the energy against the stone can cause its migration from the ureter to the renal cavity or from one calyx to another. Stone migration can increase the operative time and increases patient morbidity and healthcare cost. Some antiretropulsion devices have been created to prevent stone migration. In this context, “Virtual Basket™” technology is a result of pulse modulation during holmium laser lithotripsy in which the laser emits part of the energy to create an initial bubble, and the remaining energy is discharged once the bubble is formed so that it can pass through the already formed vapor channel.

Based on this new setting of Ho:YAG laser, we applied the Virtual Basket™ mode to HoLEP, in order to compare clinical intra and early postoperative outcomes between conventional HoLEP and Holmium laser enucleation of the prostate with Virtual Basket tool (VB-HoLEP) to treat benign prostatic hyperplasia (BPH).

Methods

This prospective randomized study enrolled consecutive patients with BPH who received an indication to HoLEP according to EAU GuideLines [1]. Ethical committee approval was obtained (n° 2019/267 ATSlNs) and a subsequent consent form was signed by each patient that entered the study (Clinical trial registration: ISRCTN72879639). A simple randomization 1:1 was used to assign each patient to an HoLEP vs VB-HoLEP procedure. Exclusion criteria were an age under 18 or over 90 years, presence of acute infection (fever more than 38° C, total leucocyte count more than 15000/dl or preoperative positive urinary culture), coexisting urethral or prostate disease and presence of bladder stones. Furthermore, all the recruited patients who refused to give consent to the study were excluded. Coagulation during the procedure was done only by the laser and not with a monopolar or bipolar resectoscope.

Both groups were treated with settings of 1.8J at 45 Hz by Cyber Ho 100 laser platform (Quanta System, Samarate, Lombardia, Italy) and 550 µm reusable fibers. Virtual Basket mode was enabled on the left pedal (used for cutting) in the second group only. In order to reduce any other difference, the same

settings combination (0.6 J at 35 Hz) was used for coagulation in both groups. The adopted technique was the traditional 3 lobes technique.

For all the procedures, we used a Storz resectoscope with 12 degrees optic, with Kuntz element (Karl Storz Tuttlingen Germany) and a guide to allow a 500 um fiber to pass.

After completing the enucleation step, the dissected tissue was morcellated with the DrillCut morcellator device (Karl Storz, Tuttlingen, Germany).

All patients were evaluated post-operatively with regards to blood loss, catheterization time, irrigation volume, hospital stay and operative time. At 3 and 6 months after surgery, patients were also evaluated by International Prostate Symptom Score (IPSS), maximum flow rate (Qmax), and postvoid residual urine volume (PVR).

Statistical analysis - Simple Block Randomization was obtained through "Adaptive Randomization" software (University of Texas) to reach a good number balance between the two groups. To reach a good allocation concealment we used a centralized service to rule all the participating centers. To avoid any bias leading in outcomes analysis participants blinding was ensured for all the hospitalization (they actually did not know which lasers was used for their enucleation) and the data were never analyzed by one of the operating surgeons.

A statistical analysis was carried out to assess patients data and outcomes. All of the reported p values were obtained by the two-sided exact method at the conventional 5% significance level. Data were analyzed with the April 2016 by R software v.3.2.3 (R Foundation for Statistical Computing, Vienna, Austria), according to previously published guidelines for the reporting of statistics. We calculated the sample size with a confidence level of 95% and a confidence interval of 5%.

Results

From June 2019 to January 2020 278 patients received the indication to be treated for BPH with an HoLEP procedure and met the inclusion criteria of the study. 21 of them refused to sign the consent form to enter the study thus leading to have 125 pts for the HoLEP group and 132 for the VB-HoLEP one. At three months 112 and 120 patients were controlled and 100 patients for each arm were able to attend the 6 months scheduled control. CONSORT flow chart Fig. 1.

Preoperative data of patient are presented in Table n.1. Early postoperative evidence are summarized on Table n. 2. We didn't see significant difference in preoperative parameters between patients in each study arm. Compared with HoLEP, VB-HoLEP resulted in less hemoglobin decrease (2.54 vs 1.12 g/dL, P = .003) and had a more rapid operative time (57.33 ± 29.71 vs 42.99 ± 18.51 minutes, P = 0.04). HoLEP and VB-HoLEP had same catheterization time (2.2 vs 1.9 days, P = 0.45), irrigation volume (33.3 vs 31.7 L, P = 0.69), and hospital stay (2.8 vs 2.7 days, P = 0.21). During the follow-up of subsequent 12 months, we didn't demonstrate a significant difference in IPSS, Qmax, PVR, and QOLS (Table n. 3).

Table n.2 presents complications rate in the two different Groups.

Discussion

HoLEP is an option for the surgical management of BPH and it's an alternative treatment to TURP or open surgery according to EAU GuideLines. One of the main advantages of HoLEP is that reduces intraoperative and post-operative bleeding, leading to a lower transfusion rate, shorter hospitalization, and less catheterization [7].

This kind of enucleation is performed with the Ho:YAG laser, which is a pulsed system with a wavelength of about 2.1 μm obtaining tissue coagulation and necrosis limited to a depth of 0.3–0.4 mm while also providing a hemostatic effect [8]. Nowadays, Ho:YAG laser is used also for stone lithotripsy, during which, the impact of the energy against the stone can cause its migration from the ureter to the renal cavity or from one calyx to another. To prevent this phenomenon, anti-retropulsion devices have been engineered, like the “Virtual Basket” mode, which is a result in pulse modulation during holmium laser lithotripsy in which the laser creates an initial bubble with the first part of its energy, and then it discharges the remaining energy once the bubble is formed so that it can pass through the formed vapor channel. In this study, we report the results of our intra and early postoperative outcomes of the application of Virtual Basket to HoLEP (VB-HoLEP) confronted to the conventional technique; we also studied the 6 months of follow-up of these patients.

Vizziello et al firstly reported their in vitro experience regarding the use of Virtual Basket in stone phantom lithotripsy [9]. The authors concluded that this mode was associated with significantly fewer events of stone migrations and a better target stability during the procedure. Another study [10] investigated this emission mode in the treatment of ureteric and renal stones. In particular, it was reported that when compared with regular mode, Virtual Basket Technology was associated with significantly less retropulsion and lower fragmentation time and total procedural time, with no significant differences in total emitted energy.

Based on these studies, this mode may grant a smoother effect not only on stones but also on soft tissues, resulting in less trauma and thus bleedings. The displacement of water medium occurred with the first pulse should further impact the overall energy transmission of laser energy to the tissues, which the second pulse withstanding a lower medium attenuation.

Because of its double pulse pattern, we further hypothesize that the use of Virtual Basket during HoLEP may result in a first energy portion creating an initial separation of prostatic tissues and the remaining energy being discharged through the engraving to further extend the incision and clot the bleeding vessels. Indeed, because the laser second pulse travels through the vapor tunnel created by the first pulse, a lower attenuation should occur, so that a stronger tissue reaction (sealing and/or incision) should develop. This system with emission of energy with two pulses fired with little time in between” seems however to allow faster and more immediate coagulation which reduces bleeding, the risk anemia and, so, the operative time. Indeed, as reported in our results, compared with HoLEP, VB-HoLEP had faster

operative time (57.33 ± 29.71 vs 42.99 ± 18.51 minutes, $P = 0.04$) and resulted in less hemoglobin decrease (2.54 vs 1.12 g/dL, $P = .003$). Although bleeding risk of BPO surgery using HoLEP is less than in other older procedures, the risk of bleeding remains. Some studies report a risk of severe hemorrhage in 5.2% of patients and a risk of bladder tamponade that required cystoscopy and evacuation of blood clots in 2.3% [11]. In some Centers, to reduce the risk of bleeding in the early post-operative time, surgeons use a bipolar resectoscope to obtain prostatic loggia coagulation. This lengthens the operating time and thus increases the risk of anesthesiologic complications. In our experience, the use of Virtual Basket could improve the coagulation with the laser allowing to omit the use of the bipolar and reduce the morcellation time thanks to a good endoscopic vision without remaining bleeding.

Moreover, HoLEP has been proven safe and effective in anticoagulated patients. The hemostatic efficacy of this kind of laser let HoLEP to be effective and safer than other BPH treatment on patients who take anticoagulant agents. Specifically, the low depth of penetration of the holmium laser limits eschar formation which can contribute to delayed bleeding seen with other BPH procedures [12]. The use of VB-HoLEP, thanks to its observed better coagulation capability, could further reduce the risk of bleeding in this kind of patients [13].

The comparison between HoLEP and VB-HoLEP during the 6 months of follow-up did not demonstrate a significant difference in Qmax, IPSS, PVR, and QOLS.

Urinary incontinence (UI) is one of the most worrying postoperative complications. Postoperative UI occurred in about 20% of patients and most of them recovered in the first year. The operative time is the first risk factor: the longer the resectoscope remains for enucleation in the urethra, the higher the possibility of sphincter damage. Some studies stated that high prostate volume, a conspicuous reduction in postoperative PSA and diabetes mellitus are significant risk factors for stress UI [14]. Various authors have suggested that postoperative incontinence is a symptomatic urge due to the damage of the fossa or it's linked to the presence of urinary tract infection, BPH-related detrusor instability, or prostatic capsule thermal injury associated to laser exposure [15]. Another risk factor for UI is the presence of a large prostatic fossa created after the removal of adenoma, because it leads to urine trapping and leakage with stress maneuvers [16]. In our experience, VB-HoLEP reduces the risk of UI, maybe because it cut the mucosa better thus significantly reducing the traction forces on the urethra.

Moreover, the long learning curve is the major negative factor that hinders widespread use of this procedure to date [17]. The inexperience of the Surgeon elevates the risk of bleeding and UI after HoLEP because of long operation time, frequent intraoperative complications and inadequate enucleation.

Because the use of VB-HoLEP proved to reduce the operative time in our experience, we speculate that the risk of UI may be reduced with this technique. Also reducing the bleeding and improving the quality of the endoscopic vision, the use of VB-HoLEP may reduce the learning curve. These aspects may be verified in some other multicentric studies.

Together with the long learning curve associated with enucleation technique reported above, the cost associated with the purchase of high power laser platforms has probably represented another factor hindering the spreading of laser enucleation. However, the possibility to use VB technology also with reusable fibers and on medium power platforms might help in fostering the spreading of HoLEP in upcoming years. Indeed, the non-inferiority of low-power HoLEP with respect to high power HoLEP has been investigated [18, 19]. For instance, Elshal et al compared 50W and 100W power HoLEP techniques, reaching comparable improvement in IPSS, Qmax, median reduction in PSA with similar perioperative and late postoperative complications [18].

There is a growing interest for new pulse modulation technologies which can potentially enhance lithotripsy effectiveness and which have been recently launched on the market [9, 20, 21]. However, so far the potential advantages of these modulations have been mainly explored in stone application, whereas little has been reported regarding the effect of these pulse modulations on soft tissue treatments. One exception consists in study of Large, who shared his experience with Moses™ technology in HoLEP [22]; he report that the use of this modality resulted in increased OR efficiency and hemostasis regardless of prostate size when compared to standard HoLEP. Both his study and ours suggest that advance pulse modulation by Ho:YAG laser can result in increased hemostatic effect.

To our knowledge, this is the first study describing the use of Virtual Basket in HoLEP, and one of the few ones reporting the use of advanced Ho:YAG pulse modulation for soft tissue applications. Further investigations by other Centers are needed in order to corroborate the findings of our study.

Limitations of this study are linked to the fact that all the procedures were not done by one only skilled surgeon. Another limitation is represented by the fact that hemostasis effectiveness was judged only based on the hemoglobin drop. Potentially, a recording of the time needed for hemostasis (for example the time with the right pedal pushed) may have represented an additional comparison term to corroborate our outcomes regarding the hemostatic capabilities. Furthermore, this study dealt with the use of a single emission settings as mentioned above.

Conclusions

In conclusion, VB-HoLEP, compared with conventional HoLEP, has faster operative time and results in less hemoglobin decrease, because of a better technique of coagulation, but there are no differences in catheterization time, irrigation volume, hospital stay and in Qmax, IPSS, PVR, QOLS at 3 and 6 months. Based on these results, we can conclude that VB-HoLEP may be better than conventional HoLEP, but for our experience in the field of laser enucleation of prostate, it may not overcome the efficacy, the safety and the early and late outcomes of thulium laser enucleation of the prostate (ThuLEP) [23].

List Of Abbreviations

BPH: Benign prostate hyperplasia
HoLEP: Holmium laser enucleation of the prostate
IPSS: International Prostate Symptom Score
LUTS: lower urinary tract symptoms
OP: Open Prostatectomy
PVR: postvoid residual urine volume
Qmax: maximum flow rate
VB: Virtual Basket
VB-HoLEP: Holmium laser enucleation of the prostate with Virtual Basket mode

Declarations

Ethics approval and consent to participate: Ethical committee approval was obtained in 2019 by “Agenzia di Tutela della Salute” Insubria (Como, Italy) required by Dept. Urology, Busto Arsizio Hospital, ASST Valle Olona (n° 2019/267 ATSlns); a subsequent consent form was signed by each patient that entered the study. All patients gave their consent for the publication of this article.

Consent for public: all authors gave the consent to publication.

Availability of data and Materials: the datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interest: The authors declare that they have no conflict of interest or any known competing financial interests.

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Authors' contributions: all authors have contributed to the information or material submitted for publication, and that all authors have read and approved the manuscript.

GB has made the study design and the critical review; MM, LB, UB and AC have been involved in data interpretation, performed the statistical analysis and drafting the manuscript; MCS has been involved in data collection; AG, CB, MS and JBR have reviewed the references; AM and MB have been involved in tables drawn; BR and EL have reviewed the manuscript.

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Authors' information:

¹ Dept. of Urology, ASST Valle Olona, Busto Arsizio, Italy.

² ESUT, European Section for UroTechnology.

³ Dept. of Urology, Ospedale Policlinico e Nuovo Ospedale Civile S. Agostino Estense, University of Modena and Reggio Emilia, Modena, Italy.

⁴ Dept. of Urology, Clinique Saint Augustin, Bordeaux, France

⁵ Dept. of Urology, SLK Kliniken, Heilbron, Germany

⁶ Dept. of Urology, Spital Limmattal, Schlieren, Switzerland

⁷ Dept. of Urology, Moscow State University, Moscow, Russia

⁸ Dept. of Urology, University of Patras, Greece

⁹ Dept. of Urology, Clinica Sant'Anna, Lugano, Svizzera

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Tables

TABLE 1: Patient's data

	Group A Holep	Group B VB Holep	p
N°	100	100	P > 0.05
Age yrs (mean ± SD)	72.1 ± 11.6	70.9 ± 12.8	P > 0.05
Preoperative Prostatic volume ml. (mean ± SD)	74.2 ± 36.2	77.1 ± 29.4	P > 0.05
PSA ng/ml (mean ± SD)	2.7 ± 4.12	2.8 ± 3.89	P > 0.05
Preoperative Hb g/dl (mean ± SD)	13.4 ± 2.45	13.9 ± 2.23	P > 0.05
IPSS (mean ± SD)	19.9 ± 7.01	18.1 ± 6.69	P > 0.05
Q max ml/sec (mean ± SD)	6.9 ± 5.54	7.1 ± 6.12	P > 0.05
Post void volume ml (mean ± SD)	118.8 ± 161.95	124.1 ± 148.92	P > 0.05

TABLE 2: Intra and Early Post Operative Outcomes and postoperative complications

	Group A	Group B	p
Operative time, minutes (mean ± SD)	57.33±29.71	42.99±18.51	p = 0.04
Haemoglobin decrease, g/dl. (mean ± SD)	2.54 ± 1.23	1.12 ± 1.78	p = 0.03
Catheterization time, days (mean ± SD)	2.2 ± 3.55	1.9 ± 2.81	p = 0.45
Continuous irrigation volume, liters (mean ± SD)	33.3 ± 24.78	31.7 ± 25.22	p = 0.69
Enucleated/Resected Prostatic Volume, gr. (mean ± SD)	47.75 ± 18.54	51.03 ± 14.84	P = 0.321
Hospital stay, days (mean ± SD)	2.8 ± 3.19	2.7 ± 2.89	p = 0.21
Complication	(n° patients, %)	(n° patients, %)	
Blood transfusion	1 (1)	0 (0)	
Post void retention	2 (2)	7 (7)	
Stress Incontinence	9 (9)	2 (2)	
Urge Incontinence	7 (7)	4 (4)	
Urethral Strictures	2 (2)	1 (1)	
Bladder injury	1 (1)	1 (1)	

TABLE 3: Postoperative Functional outcomes (after 3 and 6 months)

3 months

	Group A	Group B	p
Q max ml/sec (mean ± SD)	20.76 ± 9.78	22.42 ± 11.09	p > 0.05
IPSS (mean ± SD)	6.12 ± 3.75	5.87 ± 5.18	p > 0.05
PostVoid residual, ml (mean ± SD)	45.3 ± 25.16	42.3 ± 22.71	p > 0.05
QOLS (mean ± SD)	44.2 ± 13.22	42.9 ± 11.86	p > 0.05

6 months

	Group A	Group B	p
Q max ml/sec (mean \pm SD)	19.43 \pm 12.56	23.04 \pm 8.54	p > 0.05
IPSS (mean \pm SD)	7.34 \pm 5.43	5.45 \pm 3.24	p > 0.05
PostVoid residual, ml (mean \pm SD)	31.9 \pm 20.35	38.7 \pm 21.62	p > 0.05
QOLS (mean \pm SD)	45.6 \pm 11.59	41.8 \pm 11.77	p > 0.05

Figures

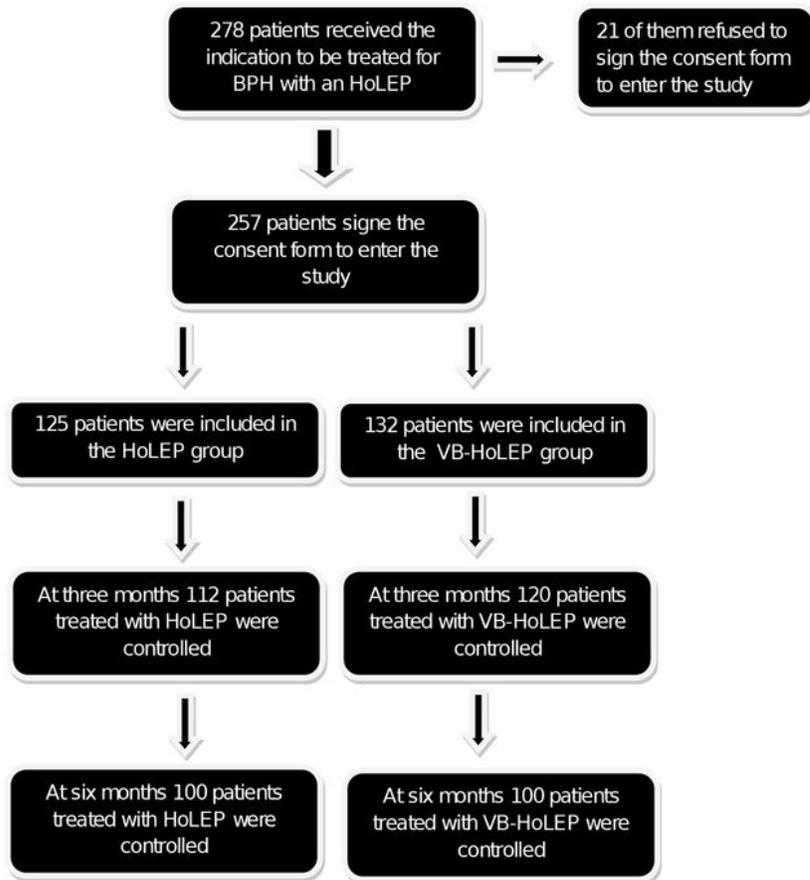


Figure 1

CONSORT flow chart.