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Citation for published version:

David, RA, Badmus, TA, Salako, AA, Asaleye, CM, Adeloje, D, Fanimi, O, Opele, JK, Laoye, A, Akinbola, IA, Igbokwe, MC, Babalola, RN & I Onyeze, C 2020, 'Diagnostic performance of Transrectal ultrasound for Prostate volume estimation in Men with Benign Prostate Hyperplasia', *International Journal of Clinical Practice*, pp. e13615. <https://doi.org/10.1111/ijcp.13615>

Digital Object Identifier (DOI):

[10.1111/ijcp.13615](https://doi.org/10.1111/ijcp.13615)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Peer reviewed version

Published In:

International Journal of Clinical Practice

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TITLE: Diagnostic performance of Transrectal ultrasound for Prostate volume estimation in Men with Benign Prostate Hyperplasia

RUNNING TITLE: Determination of prostate volume

AUTHORS: Rotimi A. David^{1a}, Tajudeen A. Badmus¹, Abdulkadir A. Salako¹, Christianah M.

Asaleye², Davies Adeloye³, Olubukola Fanimi^{2,b}, Jacob K. Opele⁴, Adeyinka Laoye^{1,c}, Ibrahim A. Akinbola¹, Martin C. Igbokwe¹, Rereloluwa N. Babalola¹, Chigozie I Onyeze¹

AFFILIATIONS

¹Urology Unit, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria

²Radiology Department, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria

³Centre for Global Health, Usher Institute, University of Edinburgh, United Kingdom

⁴National Centre for Technology Management, Obafemi Awolowo University, Ile-Ife, Nigeria

CORRESPONDING AUTHOR:

Dr Rotimi David, Urology Department, Royal Bournemouth Hospital, UK

Email: oluwarotimiaa@gmail.com

DISCLOSURE(S): Nil

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/IJCP.13615](https://doi.org/10.1111/IJCP.13615)

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DR ROTIMI ADEDEJI DAVID (Orcid ID : 0000-0003-1823-4625)

Article type : Original Paper

TITLE

Diagnostic performance of Transrectal ultrasound for Prostate volume estimation in Men with Benign Prostate Hyperplasia

ABSTRACT

Background and Aim: Despite transrectal ultrasound (TRUS) being regarded as gold-standard for prostate volume estimation, concerns have been raised in literature concerning its accuracy especially in men with above-average prostate volumes. We aimed to evaluate the performance of TRUS for prostate volume estimation in a cohort of sub-Saharan African men since they are known to have relatively large mean prostate volumes.

Methods: This was a prospective study of 77 sub-Saharan African men who had open simple prostatectomy for Benign Prostate Hyperplasia (BPH). Pre-operative TRUS determined total prostate volume (TPV) and transition zone volume (TZV). Following surgical enucleation, the adenoma was weighed (EPW) and its volume (EPV) also determined by fluid displacement. TRUS was repeated six weeks post-operatively to calculate the TRUS-estimated specimen volume (TESV).

Results: The mean EPV, EPW, TRUS-estimated TZV, TRUS-estimated TPV and TESV were 79.1 ± 62.9 mls, 79.1 ± 62.9 g, 53.3 ± 28.5 mls, 93.1 ± 48.9 mls and 69.9 ± 44.6 mls respectively. Pearson's correlation showed perfect relationship between EPW and EPV with no difference in their mean values ($r=1.000$; $P<0.001$). Pearson's correlation between TRUS-estimated TPV vs EPV, TRUS-estimated TZV vs EPV, and between TESV vs EPV were 0.932, 0.865 and 0.930 respectively ($p = 0.0000$). TRUS significantly under-estimated the TZV and TESV by 25.8ml and 9.2ml respectively; unrelated to severity of prostate enlargement.

Conclusion: TRUS underestimates prostate volume, independent of prostate size. We propose simple formulae that could be used to improve the prostate volume determination from TRUS, especially if magnetic resonance imaging is not readily available or contraindicated.

KEYWORDS: Transrectal ultrasound, Prostate volume, Benign prostate hyperplasia

'WHAT'S KNOWN?':

- Accurate estimation of prostate volume is crucial for appropriate management of men with benign prostate hyperplasia (BPH)
- Transrectal ultrasound (TRUS) is the gold-standard for prostate volume estimation. There are however conflicting reports regarding its accuracy, especially in men with above average prostate volumes.
- There are no prospective studies that have directly compared pre- and post-operative TRUS measurements with the volume of the prostatic specimen from BPH surgery

'WHAT'S NEW?':

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- Our study confirmed that TRUS underestimates the prostatic transition zone volume; and this is unrelated to severity of prostate enlargement.
 - We have derived simple formulae to better calculate volume of the prostatic adenoma from TRUS in men with BPH.
 - This should improve patient selection for medical therapy (5 α -reductase enzyme inhibitors) and surgical treatment options (Transurethral resection vs Endoscopic LASER or open enucleation procedures) in management of BPH.

INTRODUCTION

Benign prostate hyperplasia (BPH) is a common urologic abnormality and remain a major source of morbidity, impaired quality of life, loss of man hours and rarely mortality in middle aged and elderly men worldwide.[1] Accurate determination of prostate volume is important for successful management of BPH because it predicts risk of complications such as bleeding or urinary retention, guides choice of medical therapy, influences modality of surgery and has a role in monitoring following minimal invasive interventions such as prostate artery embolization.[2],[3]

Many methods can be used to estimate the prostate volume. Urethral pressure flow studies, intravenous urography, voiding cystourethrography, retrograde urethrography, urethroscopy and digital rectal examination (DRE) have been used for this purpose in the past but now largely discarded either because they are crude or unreliable.[4],[5] Similarly, the popularity of trans-abdominal ultrasonography (TAUS) for prostate volume estimation has dwindled as it is believed to over-estimate prostate volume; and the role of TAUS in BPH management is now mainly to measure post-void residual volume and also rule out upper tract complications such as hydronephrosis.[6],[7] Computed tomography scan (CT-scan) is equally not routinely recommended for volume determination as it tends to over-estimate prostate volume due to uncertainties with accurately defining the prostate dimensions and apex of the gland.[8]

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Though magnetic resonance imaging (MRI) is now generally considered the most advanced modality for determining the prostate volume, transrectal ultrasound (TRUS) is still the gold-standard globally and it remains quite popular in most parts of the world since it is cheap, easy to set up, quick to perform (usually in the office), avoids radiation exposure and is safe in patients with contra-indications to MRI such as those with claustrophobia, cardiac pacemakers or other implants in-situ. [8] In addition, TRUS offers excellent zonal anatomy of the prostate; is a useful adjunct to transrectal and transperineal prostate biopsies; and has been found to be comparable to MRI in terms of accuracy.[9] It is therefore not surprising that TRUS has been described as “an extension of the urologist’s finger” and more recently as “the urological stethoscope”; since it has become ubiquitous in urologic practice and will likely continue to retain some relevance in the foreseeable future for evaluating men with BPH.[4],[6]

Despite the sterling attributes of TRUS, its diagnostic performance for prostate volume estimation has been questioned in pockets of literature especially in men with very large prostate volumes, presumably due to difficulties with precisely delineating the cephalic border of the gland during the TRUS procedure.[10],[11] Sub-Saharan African men are generally known to have a higher mean prostate volume than other races,[12],[13],[14] so this study will evaluate the reliability of TRUS for prostate volume estimation in this sub-population, and the findings will also reasonably find application in men of other races with above average prostate volumes.

Furthermore, there have been conflicting results from previous research that have attempted to determine the relationship between the TRUS-estimated transitional zone volume (TZV) and the amount of prostatic adenomatous tissue removed during simple prostatectomy operations. While some scholars have reported that the TRUS-estimated TZV accurately reflects the obstructing prostatic adenoma;[6],[15],[16],[17],[18],[19] the findings from some other studies suggest otherwise.[20],[21] Due to the contrasting results from literature, we therefore also aimed to evaluate the relationship between both parameters in attempt to probably end the argument and put the issue to rest. This is important since the transitional zone is the main source of BPH and an accurate determination of the TRUS-estimated TZV therefore has a role in

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deciding choice of medical therapy and also proper planning for operations such as transurethral resection of the prostate (TURP), endoscopic LASER enucleation and other simple prostatectomy procedures in management of BPH.

PATIENTS AND METHODS

This was a prospective study carried out in a tertiary-care, university teaching hospital in southwestern Nigeria between June 2014 and May 2016. Following Institutional Ethics Committee approval (protocol number ERC/2014/05/14), consecutive, consenting sub-Saharan African men with BPH planned for open simple prostatectomy were recruited. Exclusion criteria were patients on 5 α reductase enzyme inhibitors, those unable to have TRUS due to painful anal conditions or previous end colostomy; and those with incidental prostate cancer histology following surgery. A minimum sample size of 44-patients was obtained based on the Leslie-Fischer's formula with 95% confidence interval and 2.6% proportion of open simple prostatectomy in our practice.[1]

Recruited patients had TRUS by same Radiology team using a MINDRAY[®] real-time model DC-7 ultrasound scanner (Shenzhen Mindray Bio-medical Electronics, Nanshan, Shenzhen, China) with 7.5MHz end fire biplanar endocavitary transrectal probe. TRUS images were obtained (Figure 1), and the transverse (width), craniocaudal (length) and anteroposterior (height) measurements of the whole prostate and transitional zone were taken in standard manner as previously described.[15] Total prostate volume (TPV) and TZV were then calculated using the prolate ellipsoid formula viz- width \times length \times height \times $\pi/6$. [15]

Open simple prostatectomy was undertaken within one week following TRUS. The choice between a retropubic or transvesical approach to the prostate was dependent on standard indications following pre-operative evaluation. All surgeries were done by same urology team and in classical manner as described.[22] Immediately following enucleation, the weight of the enucleated prostatic specimen (EPW) was determined to the nearest 0.1g using the same calibrated digital weighing scale (MYCO MZ-600, Dalman Ltd, United Kingdom). The volume of

the enucleated prostatic specimen (EPV) was then determined by fluid displacement, prior to sending off for histologic evaluation.

The volume of the residual prostate tissue (mainly peripheral zone) was determined by same blinded Radiology team post-operatively via a repeat TRUS at 6-weeks following the operation, when the edema and pain were expected to have fully subsided.[23] This post-operative TRUS-estimated residual prostate volume was subtracted from the pre-operative TRUS-estimated TPV, in order to obtain the TRUS-estimated specimen volume (TESV).

Correlations were determined using Pearson's coefficient; linear regression analysis was utilized to determine the dependence of variables on each other and mean values were compared using the paired sample t-test. Statistical analyses was done using Stata version 13.1 (StataCorp, LP, College Station, USA) and for all statistical tests, $p < 0.05$ was considered significant.

RESULTS

A total of 89 men were recruited for the study. Twelve patients with incomplete data were excluded, leaving 77 results which were analyzed. Their age range was 51-91 years (mean 69.66 ± 7.26 years). Retropubic (Millins) or Transvesical (Freyers) prostatectomy was carried out in 61% and 39% of cases respectively. The mean EPV, EPW, TRUS-estimated TZV, TRUS-estimated TPV and TESV were 79.1 ± 62.9 mls, 79.1 ± 62.9 g, 53.3 ± 28.5 mls, 93.1 ± 48.9 mls and 69.9 ± 44.6 mls respectively.

Relationship between the weight and volume of prostatic tissue

Pearson's correlation showed a perfect relationship [$r=1.000$; $p<0.001$] between the weight (EPW) and the volume (EPV) of prostatic tissue, with no differences noted between their mean values on paired sample t-test.

Relationship between TRUS-estimated TZV and EPV

Pearson's correlation revealed a very good positive correlation ($r = 0.865$, $p = 0.0000$) between the TRUS-estimated TZV and the EPV. Paired sample t-test however showed a statistically significant mean difference between the TRUS-estimated TZV and the EPV. The EPV was higher (79.1 ± 62.9 ml) compared to the TRUS-estimated TZV (53.3 ± 28.5 ml); a statistically significant difference of 25.8ml [(95% CI, 16.52 to 35.06), $t(76) = 5.54$, $p < 0.0005$]. Linear regression (Figure 2) established that the TRUS-estimated TZV accounted for 74.8% of the explained variability in the EPV, with regression equation given as:

$$\text{Enucleated prostate volume (EPV)} = -22.651 + 1.91 \times (\text{TRUS-estimated TZV})$$

Relationship between TRUS-estimated TPV and EPV

Pearson's correlation revealed an excellent positive correlation between TRUS-estimated TPV and EPV ($r = 0.932$, $p = 0.0000$). Paired sample t-test on the other hand showed that there was a statistically significant mean difference between the TRUS-estimated TPV and EPV. The EPV was lower (79.1 ± 62.9 ml) compared to the TRUS-estimated TPV (93.1 ± 48.9 ml); with a statistically significant difference of 14.0ml [(95% CI, -19.59 to -8.36), $t(76) = -4.9564$, $p < .0005$]. Linear regression established that the TRUS-estimated TPV was responsible for 86.9% of the variation in EPV (Figure 3), with regression equation given as:

$$\text{Enucleated prostate volume (EPV)} = -32.584 + 1.20 \times (\text{TRUS-estimated TPV})$$

Relationship between TESV and EPV

Pearson's correlation showed an excellent positive correlation between the TESV and the EPV ($r = 0.930$, $p = 0.0000$). Paired sample t-test revealed a statistically significant mean difference between the TESV and the EPV, with the EPV (79.1 ± 62.9 ml) being higher compared to the TESV (69.9 ± 44.6 ml); a statistically significant difference of 9.2ml [(95% CI, 3.07 to 15.32), $t(76) = 2.99$, $p < 0.0005$].

Results from further analysis

The data was split into two groups, with TRUS-estimated TPV < 100mls in one group (n = 50) and TRUS-estimated TPV >100mls in the second group (n=27). Sub-analyses of both groups were done and the results presented in Table 1.

DISCUSSION

This study suggests that contrary to previous belief, the inaccuracies associated with TRUS measurements of prostate volume are unrelated to magnitude of prostatic enlargement. In addition, we were able to derive simple formulae that could be used to correct for the poor TRUS performance and we propose that these could be incorporated into routine clinical practice for evaluating men with BPH. The strengths of our study over previous research efforts are that we related the weight and volume of the enucleated prostatic adenomatous tissue; compared the volume of the prostatic adenoma directly to the TRUS-estimated prostate volume and we also repeated the TRUS procedure post-enucleation in order to further improve accuracy of our results.

As expected, the mean prostate volume encountered in our study is relatively higher than finding from a meta-analysis in Caucasian men, but in same range as values previously recorded in Afro-Caribbean populations, consistent with earlier reports that men of African descent generally have above average prostate volumes.[1],[12],[14],[24] The perfect agreement between the weight and volume of prostatic adenomatous tissue in our study confirms a prostatic tissue density of 1.0g/ml in sub-Saharan African men. Though this is not unusual but similar to literature from other parts of the world, our study is however the first to confirm this finding in our environment to the best of our knowledge.[25],[26],[27],[28]

Of note, we found excellent correlation between the TRUS-estimated prostate volumes and the volume of the prostatic adenoma, similar to previous documentation in literature (Table 2). From a statistical viewpoint however, correlation only measures strength of the relationship between two variables so it is therefore not surprising that despite our above average correlation coefficients, we equally recorded significant differences between the mean volume

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of the adenoma enucleated during surgery and the mean TRUS-estimated prostate volumes; with TRUS underestimating the TZV. The underestimation of TZV by TRUS is difficult to explain though the traditional default has been to blame this on the severity of prostate enlargement as it has always been thought TRUS was less accurate in glands beyond 60mls due to technical difficulties with assessment of the cephalic border of the gland.[10],[11],[16],[17],[20],[21] We however conducted a sub-analysis of our data based on size criteria and interestingly, there was persistence of significant differences between the TRUS-estimated prostate volumes and the volume of the prostatic adenoma, thereby suggesting there may be other contributory factors apart from large prostate size responsible for the poor TRUS performance.

Some scholars with similar dilemma have postulated the underestimation of TZV by TRUS may be due to inter-observer sonologist variability, difficulty in accurately measuring the transition zone dimensions due to diffuse calcifications or incomplete enucleation at surgery.[15],[20],[21] These confounding issues were however precluded in our study so may not possibly explain our findings. The same team of blinded Radiologists carried out all our TRUS evaluations. We are also a high volume tertiary centre and have developed considerable expertise and proficiency in open simple prostatectomy.[1],[24] The same team of experienced urologists carried out all the operations during which we meticulously palpated the prostatic fossa post-enucleation and also carefully inspected the gross anatomy of the enucleated prostatic adenoma for completeness, thereby minimizing possibility of incomplete enucleation in our study. In addition, we factored in the post-operative TRUS measurements of the residual prostate into our calculations in order to improve methodological accuracy of our results.

A plausible explanation for the inaccuracies of TRUS may be in the modality of calculating the prostate volume following measurement of the prostatic dimensions during the TRUS procedure. The prolate ellipsoid formula is most commonly utilized for the volume calculations in clinical practice and was also used in our study.[29] It is based on assumption the prostate is an ellipsoid shape; but does not take cognizance of median lobe anatomy or unusual prostate shapes or configurations. We however believe the degree of median lobe prominence is much more important than previously ascribed and the prolate ellipsoid formula is probably not able

to adequately capture its contribution (Figure 1), with resultant underestimation of prostate volume.

Though cumbersome and probably impractical, a possible method for improving the performance of TRUS for prostate volume estimation is to take separate measurements of the median lobe and add its volume to the total prostate volume. An alternative is to make a complete shift from the prolate ellipsoid formula to less popular options such as the spheroid or the bullet-shaped formulae.[3],[30] These newer formulae are however mostly not validated, and the added fact that most ultrasound machines in clinical use are already factory configured to calculate the prostate volume using the ellipsoid formula probably makes it even more difficult to completely dump this formula in practice. We have therefore generated simple regression formulae to correct for any inherent errors associated with the prolate ellipsoid formula as this seems to be the most sensible and least disruptive option and hopefully, this should find application in estimating the prostatic adenoma volume while planning for medical and surgical management of BPH.

To conclude, TRUS underestimates volume of obstructing prostatic tissue in BPH, unrelated to size of the prostate but rather probably caused by inherent inaccuracies associated with the prolate ellipsoid formula. For practical clinical purposes, this study has generated formulae that could be used to correct for the inaccuracies of TRUS and better predict volume of obstructing prostate adenoma in men with BPH. Future research efforts should therefore probably focus on validating our formulae since they have potential to improve diagnostic performance of TRUS especially in situations where MRI is not readily available or contraindicated.

AUTHOR CONTRIBUTIONS: All the authors have contributed to this study in ways that conform to ICMJE authorship criteria. All authors had input in article draft/revision and approved the final version of the manuscript.

ACKNOWLEDGEMENTS: This manuscript is an abridged form of an unpublished dissertation submitted to the West African College of Surgeons in April 2017; in part fulfillment of requirements for award of the College's Fellowship in Urology. The study was partly sponsored by a research grant for resident doctors from the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria.

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TABLES

Table 1: Sub-analysis of prostate volumes using size criteria

a.) Analysis of group with TRUS-estimated TPV < 100mls (n=50)

Pearson's correlation			TRUS TPV vs EPV	TRUS TZV vs EPV	TESV vs EPV	
			0.8168	0.6846	0.8062	

Paired t-test			Mean	Std deviation	95% CI	Remark	p-value
1.	EPV	<i>EPV</i>	45.1	23.2	38.6	51.7	p=0.0000*
	vs	<i>TPV</i>	63.7	19.9	58.1	69.4	
	TPV	<i>Difference</i>	-18.6	3.3	-19.5	-17.7	
2.	EPV	<i>EPV</i>	45.1	23.2	38.6	51.7	p=0.0014*
	vs	<i>TZV</i>	37.1	15.3	32.7	41.4	
	TZV	<i>Difference</i>	8.0	7.9	5.9	10.3	
3.	EPV	<i>EPV</i>	45.1	23.2	38.6	51.7	p=0.2202
	vs	<i>TESV</i>	42.7	5.7	37.7	47.7	
	TESV	<i>Difference</i>	2.4	17.5	0.9	4.0	

b.) Analysis of TRUS estimated TPV > 100mls group (N=27)

Pearson correlation			TRUS TPV vs EPV	TRUS TZV vs EPV	TESV vs EPV
			0.8712	0.7295	0.8700

Paired t-test			Mean	Std deviation	95% CI	Remark	p-value
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			Mean	Std deviation	95% CI	Remark	p-value
1.	EPV	EPV	142.0	64.9	116.3	167.7	p=0.4467
	vs	TPV	147.4	38.8	132.1	162.8	
	TPV	Difference	-5.4	26.1	-15.8	4.9	
2.	EPV	EPV	142.0	64.9	116.3	167.7	p=0.0000*
	vs	TZV	83.4	22.0	74.7	92.1	
	TZV	Difference	58.6	42.9	41.6	75.6	
3.	EPV	EPV	142.0	65.0	116.3	167.7	p=0.0075*
	vs TESV	TESV	120.3	34.3	106.7	133.8	
		Difference	21.7	39.0	6.3	33.9	

*Statistically significant

Table 2: Comparison of TRUS-estimated prostate volumes and volume/weight of Adenoma from open simple prostatectomy across studies

Author	Sample size	TRUS TPV vs EPV	TRUS TZV vs EPV	Post-operative TRUS?	Difference between EPV & TRUS volume? (t-test) [% difference]
Current study	77	r=0.932; p=0.0000	r=0.865; p=0.0000	Yes- 6wks TESV: r=0.930; p=0.0000	Yes TPV (+14.0, p=0.0000) [17.7%] TZV (-25.8, p=0.0000) [32.6%] TESV (-9.2, p = 0.0038) [11.6%]
Szopinski et al[18] 2014	112	r=0.633,	r=0.945,	Yes- 3.5yrs r=0.407, p <	Yes (+1.65, p<0.001)

		p < 0.0001	p < 0.0001	0.0001	
Ajayi et al[6] 2013	46	-	r=0.594, p < 0.001	No	Not stated
Al.Jabbiri et al[26] 2012	35	r=0.661, p < 0.001	-	No	Yes (+8.81) [10.7%]
Malemo et al[12] 2011	50	-	-	No	Yes (-12.5)
Stravodimos et al[7] 2009	71	-	r = 0.904, p < 0.0005	No	No (+3.3)
Milonas et al[16] 2007	48	-	r = 0.957, p < 0.001	No	No (+2.14, p = 0.263)
Cabello et al[20] 2006	37	-	r = 0.84, p = 0.001	No	Yes (-17.1l, p = 0.001) [21.4%]
Milonas et al[17] 2003	30	r=0.893, p< 0.0001	r=0.942, p<0.0001	No	No (p = 0.6)
Baltaci et al[21] 2000	50	-	r = 0.95, p < 0.0001	No	Yes (+12.18) [17.7%]
Zlotta et al[15] 1999	34	r = 0.78	r = 0.95, p < 0.001	No	No (-5.8, p = 0.07)
Alkan et al[28] 1996	51	r = 0.729 p<0.0001	-	No	No (+4.0)
Hastak et al[19] 1982	75	-	-	Yes; 6-10wks r = 0.91	Not stated

TESV: TRUS-estimated specimen volume, TZV: Transitional zone volume, TPV: Total prostate volume, EPV: enucleated prostate volume

Negative sign: TRUS under estimated prostate volume

Positive sign: TRUS over estimated prostate volume

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Figure 1: Selected axial and sagittal images from Transrectal ultrasound

Figure 2: Scatter diagram showing relationship between Enucleated prostate volume and TRUS-estimated transition zone volume

Figure 3: Scatter diagram showing relationship between Enucleated prostate volume and TRUS-estimated total prostate volume

Table 1: Sub-analysis of prostate volumes using size criteria

Table 2: Comparison of TRUS-estimated prostate volumes and volume/weight of Adenoma from open simple prostatectomy across studies

Figure 1: Selected axial and sagittal prostate images from TRUS

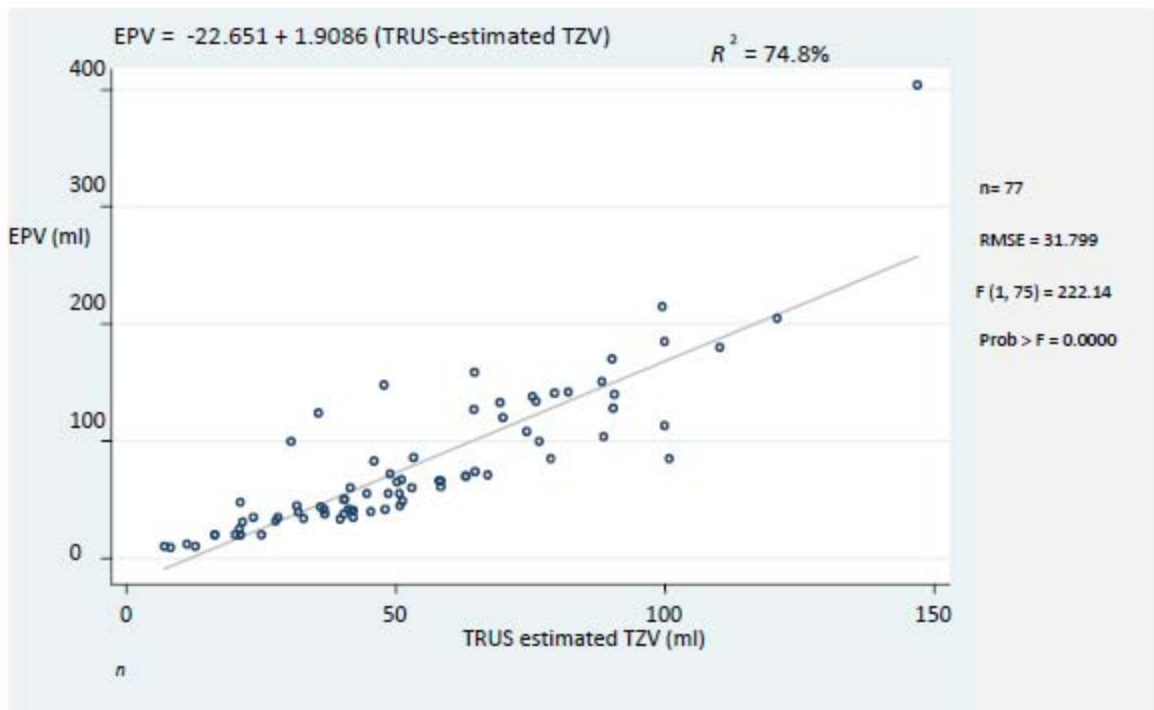
A): Axial image with well circumscribed transitional zone in central portion



B): Sagittal image with well circumscribed transitional zone (TZ) in central portion and prominent median lobe indenting on bladder

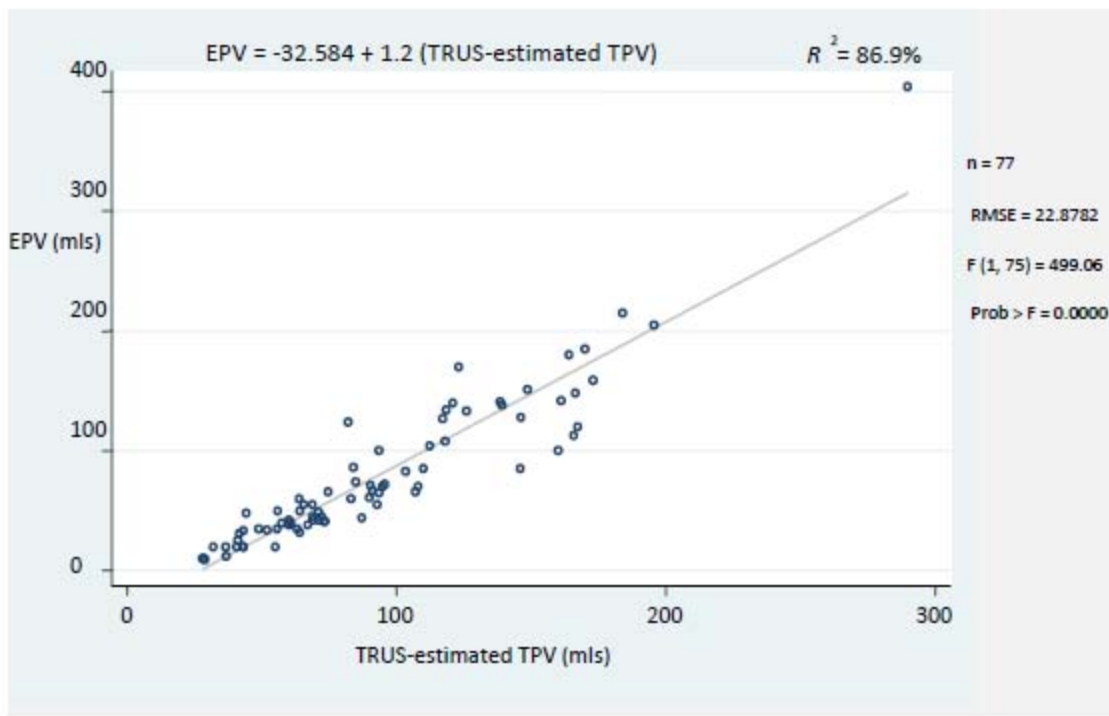


Figure 2: Scatter diagram showing relationship between Enucleated prostate volume and TRUS-estimated transition zone volume



EPV = Enucleated prostate volume; TZV = Transition zone volume, TRUS = Transrectal ultrasound

Figure 3: Scatter diagram showing relationship between Enucleated prostate volume and TRUS-estimated total prostate volume



EPV = Enucleated prostate volume; TPV = Total Prostate Volume, TRUS = Transrectal ultrasound