

Comparison of Accuracy of Frameless Stereotactic System (Neuronavigation) Against Frame Based Stereotaxy in Deep Seated Lesion of Brain

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ABSTRACT

Objective: The determination of accuracy of frameless stereotactic system against frame based stereotaxy in deep seated lesion of brain.

Study Design: Randomized controlled trial study.

Place and Duration of Study: This study was conducted at the Department of Neurosurgery, Nishtar Hospital Multan from June 2019 to June 2020.

Materials and Methods: A total of 124 patients were included in the study after informed consent and eligible in accord to the inclusion and exclusion criteria. Total participants were 124 (randomized) and were divided into two randomized groups; frame-based stereotaxy group (FB) and stereotaxy group (SG) including 62 patients in each group. The angular deviation and target distance between actual and planned trajectory were the primary outcomes in this study. Independent samples were tested through 2-tailed t-tests for statistical testing. Mann-Whitney U test was performed for non-normally distributed data while for comparison of categorical variables Chi-square or Fisher tests were performed. P-value was 0.05 as a level of statistical significance. SPSS version 23 was used for statistical computations.

Results: Trajectory length and distance were 42.32 ± 10.38 mm and 2.43 ± 1.02 mm in FB group, while 43.45 ± 11.65 mm and 2.59 ± 1.06 mm in VG group, and there was no statistically significant difference in these two parameters (p value 0.570 and 0.390, respectively). Trajectory deviation was 1.85 ± 1.28 degree in FB group and 2.63 ± 1.58 degree in VG group, and the difference was statistically significant ($p=0.003$). Table-2.

Conclusion: Patients in which brain biopsy was done, the Varioguide system can be compared to the gold standard frame-based stereotaxy on the basis of means of trajectory accuracy, complications rate and diagnostic yield.

Key Words: Frameless Neuro-navigation, Stereotaxy, Biopsy, Brain Lesion, Magnetic Resonance Imaging

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INTRODUCTION

Brain lesions are diagnosed by a routinely used procedure; Stereotactic brain biopsy¹. Frame based stereotaxy is highly precise and is a procedure of choice for biopsy and other surgical techniques of brain. On the other hand, one of its drawbacks is that it can be unpleasant for the patients and time consuming procedure when frame based stereotactic procedure with coordination frame positioned under anesthesia is used (only in few cases)^{2,3}.

Development in the stereotaxy procedure is highly attributed to the developing techniques of neuro-imaging and neuro-navigation systems. In some simple settings unguided technique was exercised. This demands, surgeon's experience and clear interactive picture display over screen must be coordinated. But in this technique natural tremors cannot be suppressed and hence overall results can vary. As a result, such procedures were introduced to frameless stereotactic systems such as supported and targeted needle or electrode due to which these are used in place of frame-based stereotaxy⁴⁻⁶.

There are three major groups of Frameless stereotactic systems; modified stereotactic devices (e.g. modified Patil frame)⁷, skull fixed stereotactic devices (e.g. Nexframe)⁸, and stereotactic systems with adjustable arm (e.g. NeuroArm)⁹. Stereotaxy with modifiable arm group includes Varioguide and its arm is attached to head clamp and head clamp can be adjusted at 3 joints. There is an instrument at the head of the arm that causes rotation and translation in three other joints, due to which fine positioning can be attained. In clinical

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settings its accuracy is not yet studied as compared to laboratory setting where its accuracy was studied. Our study aimed the determination of accuracy of frameless against frame based stereotactic system in deep seated lesion of brain.

MATERIALS AND METHODS

This is a randomized controlled trial conducted in Department of Neurosurgery, Nishtar Hospital Multan from June 2019 to June 2020. The ethical approval for the study was taken from the ethical committee of Nishtar Hospital Multan. The sample size was calculated using the reference study conducted by Bardac et al⁹. Non-probability consecutive type of sampling was used to collect the sample size. Patients with age above 18 years, willingly participating in the study, able to sign the informed consent and those with brain pathology designated to brain biopsy were included in the study. While patients with age less than 18 years, who are not able to sign the informed consent, those wanted to choose single treatment option, those with high risks to an aesthetic so were not able to undergo any procedure by anesthesia, and unable to undergo MRI. A total of 124 patients were included in the study after informed consent and eligible in accord to the inclusion and exclusion criteria. Refusal to participate and not being able to sign informed consent because of considerably altered conscious of the patients were the major cause of non-enrolment in the study. Total participants were 124 (randomized) and were divided into two randomized groups; frame-based stereotaxy group (FB) and stereotaxy group (SG) including 62 patients in each group.

Combination of Intra-op MR scan and navigation MR scan (before treatment) were imaging techniques used to measure the angular deviation and target distance, which were the primary outcomes in this study. Intra-op MR scan or after 24 hours follow-up period routine CT scan done for assessing the complications such as hemorrhage which was considered as significant if bigger than petechial hemorrhage along bioptic canal, using Karnofsky Performance Scale (KPS) for measurement of clinical deterioration, total time for procedure including placement of frame, CT scan done preoperatively, surgery, anesthesia administration and intra-op MRI, diagnostic outcome of biopsy and OR duration required were the secondary outcomes of the study. A Visual Analogue Scale (VAS) with 10 grades was used for the assessment of subjective symptoms in the patients such as expected discomfort, overall pain and overall discomfort linked to the procedure. Patient must be explained about the planned procedure, an independent neurologist perform clinical (KPS) and VAS assessment for the anticipated discomfort after randomization. Same person must have done the remaining assessments on discharge day as clinical assessment. Independent samples were tested through

2-tailed t-tests for statistical testing. Mann-Whitney U test was performed for non-normally distributed data while for comparison of categorical variables Chi-square or Fisher tests were performed. P-value was 0.05 as a level off statistical significance. SPSS version 23 was used for statistical computations.

RESULTS

Mean age of the patients was 59.56±6.76 years and 59.89±6.16 years in FB and VG group, respectively (p=0.782). FB group consisted of 32 males and 30 females while VG group consisted of 28 males and 34 females (p=0.472). Preoperative KPS was 77.92±12.04 in FB group and 80.82±6.59 in VG group (p=0.098). Mean lesion volume was 13.64±6.99 ml and 11.98±5.03 ml in FB and VG group, respectively (p=0.132). Motor deficit, aphasia, intracranial HTN, and visual disturbances were present in 9, 12, 10 and 5 patients of FB group, while in 8, 10, 16 and 11 patients of VG group (p value 0.794, 0.638, 0.186, and 0.108), respectively. There was no statistically significant difference in the baseline parameters. Table-1.

Trajectory length and distance were 42.32±10.38 mm and 2.43±1.02 mm in FB group, while 43.45±11.65 mm and 2.59±1.06 mm in VG group, and there was no statistically significant difference in these two parameters (p value 0.570 and 0.390, respectively). Trajectory deviation was 1.85±1.28 degree in FB group and 2.63±158 degree in VG group, and the difference was statistically significant (p=0.003). Table-2.

Table No.1: Baseline data

Variable	FB (n=62)	VG (n=62)	P value
Age	59.56±6.76	59.89±6.16	0.782
Gender	32/30	28/34	0.472
Pre-op KPS	77.92±12.04	80.82±6.59	0.098
Lesion volume, ml	13.64±6.99	11.98±5.03	0.132
Motor deficit	9	8	0.794
Aphasia	12	10	0.638
Intracranial HTN	10	16	0.186
Visual disturbance	5	11	0.108

Data is as mean ±standard deviation or number

Table No.2: Trajectory data

Variable	FB (n=62)	VG (n=62)	P value
Trajectory length, mm	42.32±10.38	43.45±11.65	0.570
Trajectory distance, mm	2.43±1.02	2.59±1.06	0.390
Trajectory deviation, degree	1.85±1.28	2.63±158	0.003

Data is as mean ±standard deviation

Table No.3: Procedural and outcome data

Variable	FB (n=62)	VG (n=62)	P value
Procedure length, min	77.16±18.33	56.51±13.24	<0.001
Surgery length, min	42.87±8.05	56.51±13.24	<0.001
Overall pain	1.92±0.94	1.68±0.97	0.163
Overall discomfort	2.26±0.85	1.84±0.83	0.006
KPS on discharge	81.24±9.05	78.82±5.98	0.082

Data is as mean ±standard deviation

Total procedure length was longer in FB group than in VG group (77.16±18.33 min vs. 56.51±13.24 min) with statistically significant difference ($p<0.001$). Surgery duration was significantly shorter in FB group than in VG group (42.87±8.05 min vs. 56.51±13.24 min, $p<0.001$). Overall pain was 1.92±0.94 and 1.68±0.97 in FB and VG group, respectively, with statistically insignificant difference ($p=0.163$). Overall patient discomfort was 2.26±0.85 in FB group and 1.84±0.83 in VG group, and the difference was statistically significant ($p=0.006$). KPS on discharge was 81.24±9.05 and 78.82±5.98 in FB and VG group, respectively, with statistically insignificant difference ($p=0.082$). Table-3.

DISCUSSION

In a previous study by Ringel et al, measurement of the accuracy of Varioguide system was done on a phantom [10]. Another study by Giese et al used specially designed agarose model for studying the Varioguide system, which was used for chemotherapy of brainstem via placement of 33 probes [11]. In this study another 32 probes were positioned into anatomical specimens. T1W MR Scan and Thin-slice CT were used for assessing the placement accuracy with mean total target deviations on CT scan and on MR scan were 3.1 ± 1.2 mm and 2.8 ± 1.2 mm respectively, in agarose model. Total target deviation in case of anatomical specimens for CT and MR scan were 1.95 ± 0.6 mm and 1.8 ± 0.7 mm respectively. Another study conducted by Bjartmarz et al used frameless and frame-based technique to compare the DBS electrode placement¹². In their study bilateral DBS electrode placement into ventrolateral thalamus was done in 14 patients having essential tremors. The total target deviation for both the frameless technique and the frame-based technique ($p < 0.05$) was 2.5 ± 1.4 mm and 1.2 ± 0.6 mm, respectively. Even though the difference between the deviations of both methods was considerable, due to same clinical findings, authors suggested the small difference that were observed did not affect the overall clinical results

of treatment of essential tremors and both methods are feasible.

The planned targets and frame-based stereotactic system showed same deviation when Nexframe was used in 5 patients for the frameless stereotaxy use for subthalamic DBS nucleus and as accuracy of Nexframe was studied by Fukaya et al.⁸ Comparative study for Nexframe and CRW frame was conducted by the Kelman et al¹³ that showed the target deviation for these methods was 2.78 ± 0.25 mm (Nexframe) and 2.65 ± 0.22 mm (CRW frame). In another study by, Konrad et al.¹⁴ over a large setting including 263 patients, a skull-fixed stereotactic system device was used for insertion of 497 DBS, showing mean target error of 1.99 ± 0.9 mm. However, the findings only included 75 patients who had post-op CT scan. The point deviation calculated by the system was only 0.52 ± 0.44 mm as concluded by Ringel's study¹⁰. On the other hand, he found that there was 0.4 – 6.6 mm 12-16 of localization errors for different imaging modalities and frames in his literature review while the frameless systems were associated with an error which ranged between 0.33 and 3.86 mm^{15,16-19}. Single-center nature of this study is the main limitation, along with the low number of patients being another limitation of this study. However, primary outcomes are a reason of empowerment of this study. Extremely low number of complications is the secondary outcomes of this study.

CONCLUSION

Patients in which brain biopsy was done, the Varioguide system can be compared to the gold standard frame-based stereotaxy on the basis of means of trajectory accuracy, complications rate and diagnostic yield. Along with this patients acceptance towards the Varioguide system is higher than frame-based stereotaxy.

Author's Contribution:

Concept & Design of Study:	Syed Zahid Hussain Shah
Drafting:	Shoaib Saleem Khan
Data Analysis:	Muhammad Aamir
Revisiting Critically:	Syed Zahid Hussain Shah, Shoaib Saleem Khan
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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