

A randomized controlled trial of use of papaverine in non graft cephaloradial arteriovenous fistula surgery for hemodialysis patients.

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Abstract: We conducted a randomized controlled trial of the using papaverine during creation of non graft cephaloradial arteriovenous fistula with the non usage of papaverine. Results: A total population of 134 patients on maintenance dialysis we chosen and the results are in the non papaverine group had a 7.35% failure rate when compared to the papaverine group of 1.53% failure rate. A difference of 5.81% was noted in the failure rate. Conclusion: Hence the use of papaverine as a topical vasodilator has a improve results in dialysis patients undergoing arteriovenous fistulas.

Keywords: arteriovenous fistula, AV fistula, surgical fistulas, papaverine, hemodialysis

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I. Introduction:

The patency of the arteriovenous fistula is very vital for a patient on hemodialysis. And the patency rate is multi factorial dependent may be patient factors and surgeon related factors. And the caliber of the vein, arterial vessel wall condition and also the surgical technique. And out of the most important factor is the vein caliber and pliability. And good vein caliber can give very good result for long term patency rate of a arteriovenous fistula.

II. Methods and Materials

A randomized controlled clinical trial.

A sample size to determine the clinical superiority was 112 and 134 patients is a significant sample size for randomizations. Randomized by a lot picking system and patients divided to papaverine and non papaverine group during creation of cephaloradial arteriovenous fistula. A consent taken and all patients underwent the routine standard protocol except the papaverine group used the topical spray of papaverine during the surgery. All patients who consented were included in the study and those not consented excluded from the study. A total of 134 chronic renal failure patients were randomized.

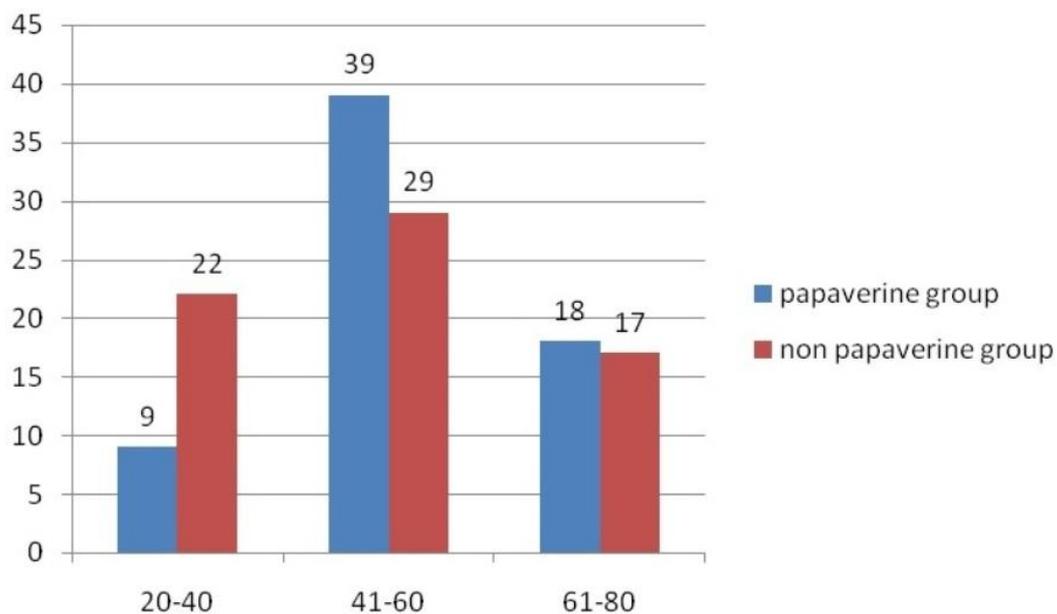
Statistical analysis

Graphs generated in Microsoft excel and both groups were compared using Chi-square test or Fischer's exact test. The data related to continuous variables were compared using Independent Student t-test. All non-Gaussian variables were compared with Mann-Whitney U test. One-way repeated measures of ANOVA were used to compare changes in continuous variables over time in both groups and two-wayrepeated measures of ANOVA were used to compare changes in categorical over time between groups. Correlation analysis was carried out to assess the association of continuous variables. Regression analysis was used to identify the factors associated with the outcome. All statistical analysis was carried out for two-tailed significance and p-value < 0.05 was considered significant.

III. Results

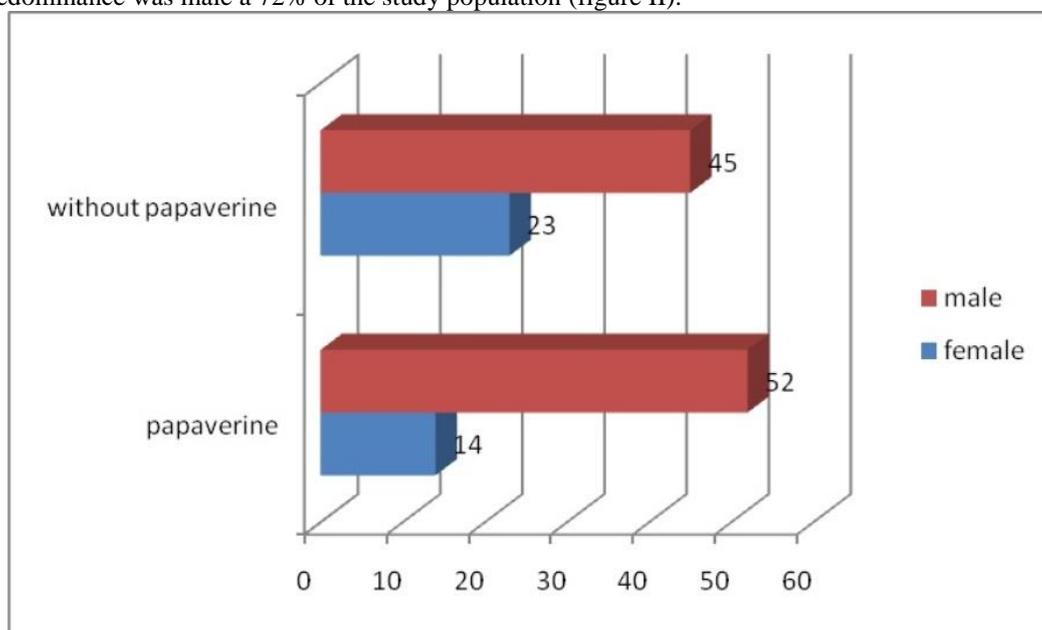
Age distribution

A total of 134 out of which the 50% of population belonged to the age group 41 to 60 year's age (figure I). And number in papaverine group and the non papaverine were 66 and 68 patients respectively.



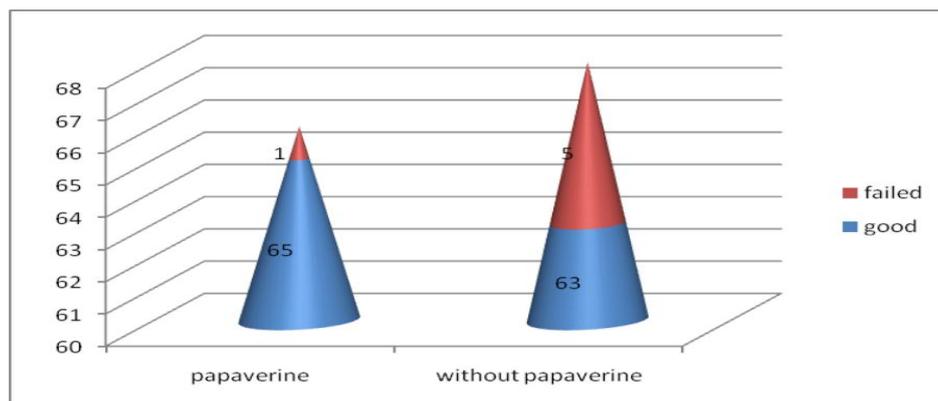
Sex distribution

Sex predominance was male a 72% of the study population (figure II).



Outcome of the trial

The non papaverine group had a 7.35% failure rate and the papaverine group of 1.53% failure rate (figure III). A difference of 5.81% was noted in the failure rate.



IV. Discussion

We randomized 134 patients for the study the significant sample size for clinical superiority is 112 [1]. Papaverine is an opium alkaloid antispasmodic drug, used primarily in the treatment of visceral spasm, vasospasm occasionally in the treatment of erectile dysfunction.

Papaverine has also been demonstrated to be a selective phosphodiesterase inhibitor for the PDE10A subtype found mainly in the striatum of the brain. When administered chronically to mice, it may produce an antipsychotic effect [2, 3].

The need for the lowest failure is the aim of all surgeons as far as arteriovenous fistula is concern. Early failure rates are common with arteriovenous fistula and many the literature are available like the Da Silva et al [4] had a 15% early failure rates and suggested adjunct medical management following avf creation. Baldrati et al [5] found that a dialysis pre-arteriovenous fistula reduce the early failure rate to 13.5%. Similarly studies Sozudogru et al [6] and Ozkoleli et al [7] have 18% and 18.8% respectively. And patency variable [8] is a constant in all the studies.

We studied a total population of 134 patients on maintenance dialysis we chosen and the results are in the non papaverine group had a 7.35% failure rate when compared to the papaverine group of 1.53% failure rate. A difference of 5.81% was noted in the failure rate.

V. Conclusion

From our randomized controlled clinical trial of the using papaverine during creation of cephaloradial non graft arteriovenous fistula with the non usage of papaverine we found in a population of 134 dialysis patients undergoing arteriovenous fistulas the use of papaverine as a topical vasodilator has a improved results of 5.8% compared to non use of papaverine. Hence a routine use of papaverine is recommended for during creation of arteriovenous fistulas or vascular procedures.

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