Negative Studies Published in Indian Medical Journals are Underpowered

51 inconclusive studies published in 14 Indian medical journals were analyzed for adequacy of power by post hoc power calculation. No study was found to be adequately powered (>80%) at small effect size, only 8 studies were adequately powered for medium effect size and 30 studies were adequately powered at large effect size.

Inconclusive studies published in medical journals should have proper reporting of power and sample size so that their validity can be assessed by readers. A study may become inconclusive because of two main reasons one there may be actually no difference between the groups for the outcomes or sample size/power of study is not adequate to measure that difference. Results of a study can only be considered valid when the study is adequately powered to see the difference between the groups [1]. It has been observed in the studies done for articles published in westerns medical journals that many of the studies including inconclusive and negative studies are not adequately powered to detect difference between the groups [2,3]. Publications of these underpowered studies are consi-dered as unethical because they exposes the patients to adverse effects of interventions but unable to detect which intervention is superior [4,5]. Though many studies are published for assessment of articles published in western medical journals for adequacy of power, similar data are lacking for the Indian Medical Journals. So this study was designed with the aim of critical evaluation of inconclusive studies published in 14 Indian medical journals for adequacy of power by post hoc power calculation.

All the Pubmed indexed journals subscribed by central library of our institute were taken into consideration. These journals were Indian Pediatrics (IP)(inconclusive studies 6/13), Annals of Indian Academy of Neurology (AIAN)(5/13), Indian Journal of Orthopedics (IJ Ortho) (inconclusive studies 7/63), Indian Journal of Critical Care Medicine (IJCCM) (inconclusive studies 2/15), Indian Journal of Dermatology, Vanereology and Leprology (IJDVL) (inconclusive studies 4/16), Indian Journal of Nephrology (IJN) (inconclusive studies 1/14), Indian Journal of Dermatology (IJD) (inconclusive studies 3/21), Indian Journal of Ophthalmology (IJO) (inconclusive studies 1/15), Indian Journal of Urology (IJU) (inconclusive studies 8/24), Indian Journal of Anesthesia (IJA) (inconclusive studies 13/46), Indian Journal of Psychiatry (IJ Psy) (inconclusive studies 1/8), Indian Journal of Medical Research (IJMR) (inconclusive studies 0/12), Indian Journal of Medical Science (IJMS) (inconclusive studies 0/6) and Indian Journal of Community Medicine (IJCM) (inconclusive studies 0/10). All the original articles published in 2009 from these journals were evaluated to identify inconclusive studies. Studies were considered inconclusive studies on the basis of these criteria-one: primary outcome is not statistically significant, second: most important outcome is not statistically significant (if primary out come is not reported). Post hoc power of all these inconclusive studies were calculated with the help of G Power software [6]. and recalculation was done by another author (k = 0.84). This software calculates post hoc power on the basis of Cohen's criteria of small, medium and large effect size [7]. Studies whose power was found to be less than 80% were considered underpowered.

51 studies were found to be inconclusive out of total 276. Out of these studies no study was found to be adequately powered (power >80%) for small effect size. Only 8 (15.6%, 95% CI 8.1 to 28) studies were adequately powered for medium effect size and 30 (58.8%, 95% CI 45.1% to 71.2%) studies were adequately powered for large effect size. 22 (43.1%, 95% CI 30.5% to 56.7%) studies were under-powered even for larger effect size.

Similar results were obtained in studies done for negative studies published in western journals. In a study done by Keen, *et al*. [2] it was observed that out of all negative studies published in rheumatology literature in 2001-2002, only 50% studies had adequate power [2]. In a similar study done by Freedman, *et al*. [8] it was observed that out of 25 negative studies published in orthopedic journals, no study had adequate power (80%) for small effect size according to cohens criteria and only 48% studies had adequate power for large effect size. Bedard, *et al*. [9] observed that out of 423 clinical trials only 45 (10.6%), 138 (32.6%) and 233 (55.1%) trials were adequately powered for small, medium and large effect size, respectively [9].

We can conclude that most of the inconclusive studies published in Indian medical journals are underpowered to see the actual difference between the groups; thus their validity is questionable.

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Profile of Acute Renal Failure in Children in Kashmir

We report on the etiology and the short term outcome (3 month) of children with acute renal failure (ARF) at a tertiary care centre in north India. Acute tubular necrosis was the commonest cause of ARF (33%) especially in children <5 years of age; while in children >10 years, glomerulonephritis was the commonest cause. The overall mortality rate was 20%.The outcome at 3 months showed normal renal function in 72 patients and CKD in 5 patients. Three patients were lost to follow-up.

Key words: *Acute tubular necrosis, Glomerulonephritis, India.*

Acute kidney injury (AKI; previously called acute renal failure) is characterised by a usually reversible increase in the blood concentration of creatinine and nitrogenous waste products and by the inability of the kidneys to appropriately regulate fluid and electrolyte homeostasis [1].

We conducted a study in the department of Nephrology and Neonatology, SKIMS, Soura, Srinagar Kashmir over a period of two and half years from 2006 to 2008.Hundred (100) cases of children up to the age of 18 years with ARF admitted in SKIMS were studied. The minimum age was 1 day and the maximum age was 18 years. 36% patients were <2 years, 6% 2-5 years, 27% 5-10 years and 31% >10 years.The diagnosis of ARF was based on rapidly progressive azotemia (rise of serum creatinine by at least 0.5/dL/day or BUN rise by 10 mg/dl/day or serum creatinine more than 2 mg/dl and usually but not always associated with oliguria [2,3]. After providing initial emergency care, detailed history, physical examination and investigations were carried out to determine the cause of ARF. Oliguria was the commonest clinical presentation present in 60% patients followed by edema (45%). Anuria was present in 13% of patients.33% were dehydrated with 11% having severe dehydration. 20% patients had hypertention on presentation.

***Table* I** shows the etiology of ARF and the associated mortality. ATN was the commonest (33%) cause of ARF in our patients especially in children <5 years of age. Sepsis was the commonest cause of ATN (45%) followed by birth asphyxia (18.18%) and acute gastroenteritis (AGE) (15.15%). Above 10 years,glomerulonephritis was the leading cause (16%) of ARF. Post-operative and post-renal causes of ARF comprise very low percentage (each 8%); same observations have been made by Srivastava, [4]. Drug induced renal failure comprise 5% of cases. Most cases were managed conservatively, while RRT in the form of peritoneal and hemodialysis was done in 20 cases. Mortality rate was 20%; same as observed by Ihab Sakr Shaheen, *et al*. [5]. ATN has the highest proportion of death (p.value 0.003) comparable with other study [6]. Survival was better in older children than in younger ones.

We conclude that even today, sepsis is the most common cause of ARF followed by AGE in this part of the world. If these conditions are treated early and