Letter to the Editor

Dear Sir

In his paper 'Ano-vesical reflex: role in inducing micturition in paraplegic patients' (*Paraplegia* 32 (1994) 104–107), Dr A Shafik describes a variety of invasive investigations and procedures carried out on 14 healthy volunteers and seven patients with complete spinal cord transection. I am concerned about the ethics of this study, particularly as it affects the 14 volunteers. They were subjected to a physical examination which included rectal examination, barium enema, colonoscopy, plain x-ray, intravenous urography, urethral catheterisation, balloon dilatation of the anal sphincter, bilateral pudendal block and administration of phentolamine (dose and route not stated). No subsequent reference was made in the paper to the barium enema, colonoscopy or intravenous urography and it is not clear what purpose these investigations served. It is stated that the volunteers signed an informed consent before entering the study but it is not stated how much explanation was given regarding the nature of the investigations and their purpose. Was this study subjected to the scrutiny of an ethics committee?

Now that this study has been published in *Paraplegia* I feel that readers of this journal are entitled to an adequate explanation of the ethics of this study.

Mr G J Fellows
Consultant Urological Surgeon MS FRCS
Department of Urology
The Churchill Hospital
Oxford OX3 7LJ, England

and

National Spinal Injuries Centre
Stoke Mandeville Hospital
Aylesbury, Bucks HP21 8AL, England

Reply from Dr Shafik

Dear Sir

Thank you for sending me Mr Fellows' letter with comments on my recent paper.

In reply to the points raised I would like to clarify the following:

The 14 healthy volunteers had a past history of bilharzial infestation which may affect the colon and urinary tract. They came to the hospital for a check-up of the colon and urinary tract for possible late manifestations of bilharziasis, mainly liver cirrhosis and bilharzial bladder cancer. As a routine, they were subjected to physical examination as well as rectal examination, barium enema, colonoscopy, plain x-ray and intravenous urography. The results of all of these investigations were normal.

They then volunteered to do the urethral and anal balloon catheter testing as well as pudendal block and phentolamine (Regitine, 5 mg IV) administration. Before signing their consent, each subject was instructed individually on the aim of the study, the methods and the possible side effects.

The study was approved by our faculty review board.

We hope that we have hereby answered satisfactorily Mr Fellows' questions, and that the results of the investigations are of interest to readers.

Professor Ahmed Shafik MD PhD
Professor and Chairman
Department of Surgery and Research
Faculty of Medicine
Cairo University
Cairo, Egypt