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METHOD AND APPARATUS FOR DISSOLVING RENAL CALCULI

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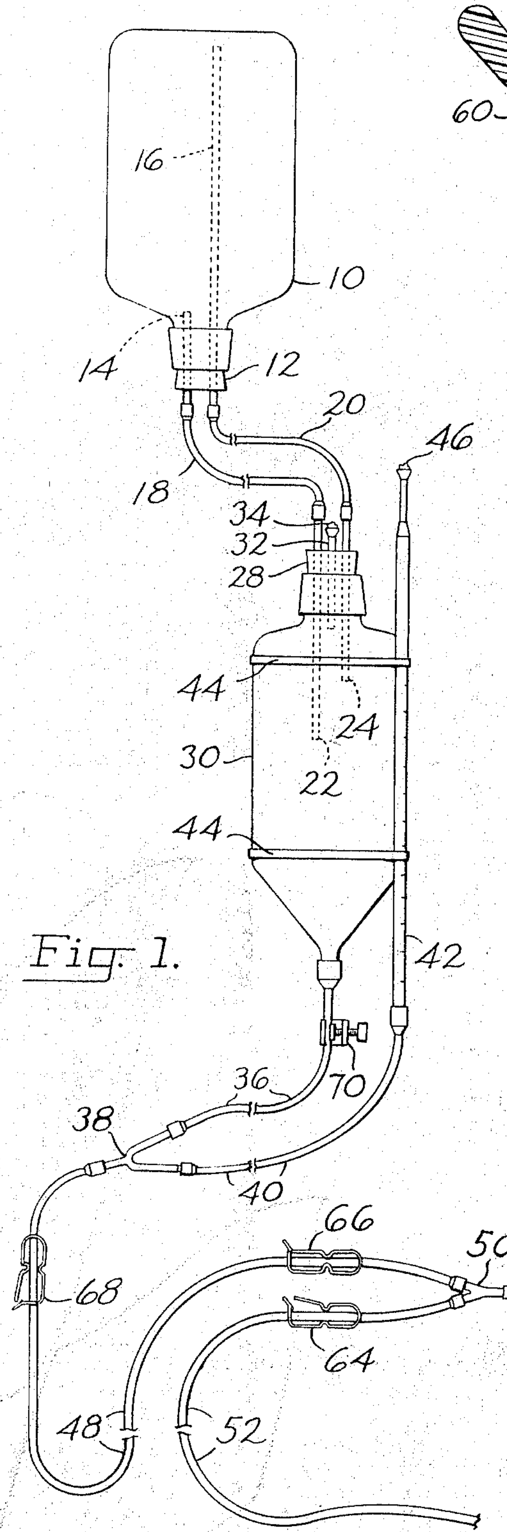

Fig. 1.

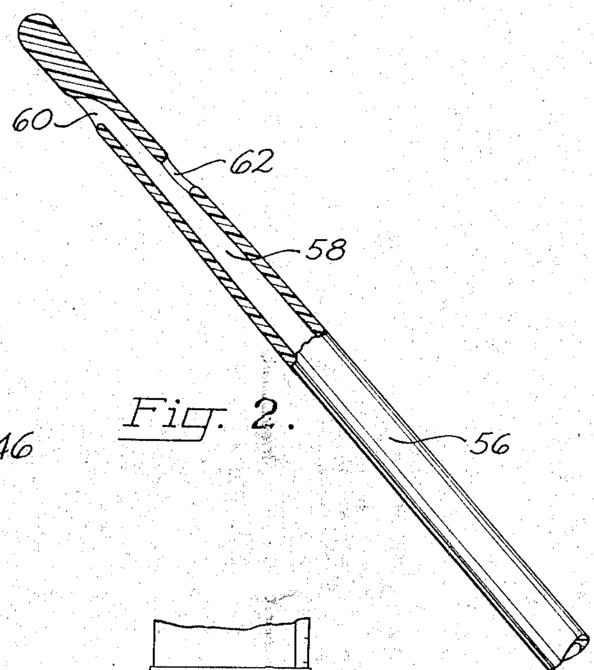

Fig. 2.

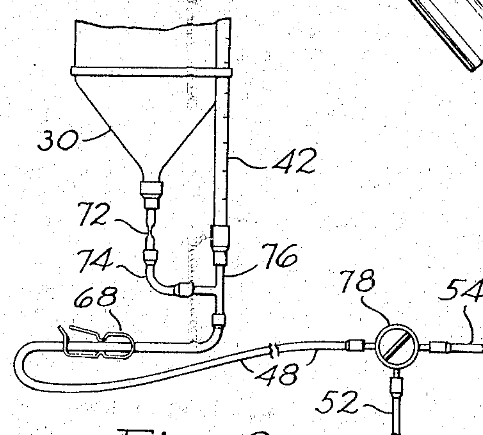

Fig. 3.

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METHOD AND APPARATUS FOR DISSOLVING RENAL CALCULI

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This invention relates to the dissolution of renal calculi, and more particularly to a method and apparatus for dissolving renal calculi with maximum effectiveness, efficiency and safety.

The removal of renal calculi by dissolution, rather than by open operation, is of advantage in many circumstances. For example, it has important application in the recurrence of calculi after operative removal, when reoperation would be technically difficult, when fragments remain after operative removal, when renal lithiasis complications occur in advanced pregnancy, and in poor operative risks. It is useful when operative removal of large staghorn calculi might result in extensive damage to, or loss of, the kidney, and for the removal of small stones in minor calyces which cause recurring hematuria and infection but the operative removal of which might result in unjustifiable parenchymal damage.

Dissolution of renal calculi has been achieved heretofore by inserting two or more ureteral catheters or a double lumen catheter into the renal pelvis and introducing a calculus solvent into the renal pelvis through one of the catheter lumens while continuously removing the solvent through the one or more other catheter lumens. This procedure has been found inadequate because of experienced disadvantages and dangers. Multiple ureteral catheters may sometimes not be insertable without hazard due to the restricted size of the ureteral caliber. Smaller caliber catheters become too easily obstructed, and higher pressures are required to provide equivalent flow through the circuit of the smaller catheters. The outflow catheter frequently becomes obstructed, thus resulting in dangerously increased intrarenal pressures. Even the normal elevated pressure attending the continuous flow of solvent may be a factor in producing ischemic necrosis, as well as absorption of chemical products of the calculus, with resulting hyperphosphatemia. The introduction of bacteria into the kidney may result upon breaking of the connections when it is necessary to open the lumen of the outlet catheter by hand syringe irrigation.

The foregoing and other deleterious factors have been encountered and reported, with the result that the procedure has been abandoned.

Accordingly, it is the principal object of the present invention to provide a method and apparatus for the effective, efficiency and safe dissolution of renal calculi, with the elimination of the foregoing deleterious and dangerous factors.

Another important object of this invention is the provision of a method and apparatus for dissolving renal calculi, which involves the use of only one ureteral catheter to perform the dual function of introducing the calculus solvent to and removing it from the renal pelvis.

Still another important object of the present invention is the provision of a method and apparatus for dissolving renal calculi, which method and apparatus insures the limitation of intrarenal pressure to a safe level.

A further important object of this invention is the provision of a method and apparatus for dissolving renal calculi, which method and apparatus requires minimum professional attention, being operable with complete effectiveness and safety by the patient with a minimum of instruction.

A still further important object of this invention is the

provision of a method and apparatus for dissolving renal calculi, which method and apparatus involves a minimum of equipment, all of which is commercially available.

The foregoing and other objects and advantages of this invention will appear from the following detailed description, taken in connection with the accompanying drawing in which:

FIG. 1 is a foreshortened view in side elevation of apparatus exemplifying and embodying the features of the present invention;

FIG. 2 is a fragmentary plan view, partially sectioned and on an enlarged scale, showing details of construction of a conventional catheter; and

FIG. 3 is a fragmentary foreshortened side elevation of a modified form of apparatus embodying the features of this invention.

In its basic concept, the present invention involves the introduction into the renal pelvis, through a single catheter, of a quantity of calculus solvent not substantially exceeding the intrarenal capacity, retaining said solvent therein for a period of time sufficient to effect at least partial dissolution of the calculi, removing said quantity of solvent from the renal pelvis through said single catheter, and repeating the foregoing sequence of steps over a period of time sufficient to effect dissolution of the calculi.

Among the solvents suitable for dissolving renal calculi are the various sodium and other alkali metal salts of ethylene diamine tetra acetic acid. Another solvent is known by the trademark Renacidin.

Referring now to the drawing, the apparatus illustrated in FIG. 1 includes a supply reservoir adapted to contain a substantial quantity of calculus solvent. In the embodiment illustrated, the supply reservoir is in the form of an inverted flask **10** closed at its bottom open end with a stopper **12** through which extends a fluid filler tube **14** and an air tube **16**. The outlet tube terminates at its upper end adjacent the lower end of the flask, and the air inlet tube terminates at its upper end adjacent the upper end of the flask.

The tubes **14** and **16** project downward through the stopper and communicate through the respective flexible tubes **18** and **20** with the upper ends of the corresponding fluid filler tube **22** and air tube **24**, respectively. These tubes extend through a stopper **28** which closes the upper end of the measuring flask **30**. The air tube **24** terminates at its lower end adjcent the upper end of the measuring flask, and the fluid filler tube **22** terminates at its lower end a distance below the air tube. An air vent tube **32** extends through the stopper **28** and communicates the upper end of the measuring flask with the atmosphere. The outer end of the tube **32** is loosely plugged with cotton or other suitable material **34** to exclude solid contaminants from the measuring flask.

By means of the foregoing arrangement of the tubes, the solvent in the measuring flask is maintained at a substantially constant level adjacent the lower end of the air tube **24**, as is well known.

The lower constricted open end of the measuring flask **30** is connected to one end of the flexible tubing **36**, the opposite end of which is connected to one leg of a triple branch coupling **38**. Although this coupling may take the form of a T, or other configuration, the Y-shaped coupling is illustrated merely for convenience.

A second leg of the coupling **38** is connected to one end of the flexible tubing **40** the opposite end of which is connected to the bottom end of an elongated burette tube **42** which, conveniently, is supported by the measuring flask **30** by tapes **44** or other suitable means. In the preferred arrangement illustrated, the zero graduation on the burette is aligned horizontally with the established level of solvent in the flask **30**, so that the burette will fill each time to the substantially constant level of the zero graduation.

the upper open end of the burette is plugged loosely with cotton or other suitable material 46.

The third leg of the coupling 38 is connected to one end of the flexible tubing 48, the opposite end of which is connected to one leg of a second triple branch coupling 50. A second leg of this coupling is connected to one end of the flexible tubing 52, the opposite end of which communicates with a discharge flask or other suitable drain (not shown).

The third leg of the coupling 50 is connected to one end of a flexible tubing 54, the opposite end of which is connected to one end of a conventional ureteral catheter 56. The opposite end of the catheter generally is closed (FIG. 2), and the adjacent end of the internal bore 58 of the catheter usually communicates with a pair of longitudinally spaced openings 60, 62 which extend through the catheter wall at diametrically opposed positions, to minimize the possibility of obstruction, as is well known.

The flexible drainage tube 52 is provided with a drainage control valve 64 by which the tube may be closed or opened. There are many types of valves suitable for this purpose, the Davol clamp valve illustrated being preferred for its simplicity and ease of operation with one hand. In similar manner the flexible infeed tubing 48 is provided with an infeed control valve 66 for controlling the introduction of solvent to the catheter 56 and hence to the renal pelvis. The drainage control valve 64 and infeed control valve 66 preferably are located for convenient manipulation by one hand of the patient, as explained more fully hereinafter.

The infeed tube 48 preferably is also provided with a shutoff valve 68 similar to the valves 64 and 66, but positioned remotely from the patient for use by the physician to either start or stop the treatment.

The flexible tubing 36 connected to the outlet end of the measuring flask 30 is provided with an adjustable valve 70 for regulating the flow rate of solvent from the measuring flask to the burette metering tube 42. This valve is adjusted to constrict the tubing to the extent that the flow of solvent from the measuring flask to the burette (when valve 66 or valve 68 is closed) effects filling of the burette to the zero graduation in a substantial length of time, for example ten minutes. By restricting the flow to this extent, it will be apparent that an insignificant volume of solvent will flow from the measuring flask when the infeed control valve 66 is opened to introduce a measured volume of solvent from the burette to the renal pelvis. This measured volume of solvent is predetermined not to substantially exceed the intrarenal capacity, and this volume may be identified visually by appropriate graduations on the burette.

The supply reservoir 10 and measuring flask 30 preferably are mounted upon a mobile or otherwise portable support (not shown) for easy transport of the apparatus to the bedside of the patient. In use, the catheter 56 is inserted into the renal pelvis, the drainage tube 52 is placed in a discharge flask or other drain source, and the drainage control valve 64 and infeed control valve 66 are positioned for convenient access and manipulation by one hand of the patient. With these valves closed and the shut off valve 68 open, the physician then instructs the patient to open the infeed control valve 66 until the level of solvent in the burette drops to a predetermined graduation, for example to the 10 cc. graduation. The patient then is instructed to close the infeed control valve and to then wait a predetermined time, for example ten minutes, before opening the discharge control valve 64. The solvent thus is retained in the renal pelvis for said ten minutes, or other suitable period of time sufficient to effect at least partial dissolution of the calculi. The discharge control valve 64 then is opened for a period of time, for example two minutes, to permit drainage of the solvent from the renal pelvis. Thereafter, the discharge control valve is closed and the infeed valve is opened to admit a second predetermined volume of solvent from the burette to the renal pelvis, as previously explained. This cycle of operation is repeated continuously on a prescribed schedule, by the patient during his waking hours, or otherwise by an attendant.

During the ten minutes or other retention time following the closure of the infeed control valve 66, in which the solvent is retained in the renal pelvis to effect dissolution of the calculi, the burette 42 is slowly filled to the zero graduation with solvent from the measuring flask 30. The burette thus is made ready to supply a subsequent predetermined quantity of solvent to the renal pelvis upon completion of the preceding cycle. Upon opening of the infeed control valve 66, this predetermined quantity of solvent is introduced into the renal pelvis in a relatively short period of time, for example a few seconds, after which the infeed control valve is closed. Because of this relatively short infeed time, the solvent admitted from the measuring flask is insignificant.

Moreover, since the volume of solvent introduced through the renal pelvis from the burette is predetermined not to substantially exceed the intrarenal capacity, intrarenal pressure is assured of being maintained at a safe level.

In the embodiment illustrated in FIG. 3 the bottom open end of the measuring flask 30 is connected through a constricted tube 72 and flexible tube 74 to one leg of a T-coupling 76, a second leg of which is connected to the bottom end of the burette tube 42. The constricted tube 72 performs the same function as the adjustable regulator valve 70 described hereinbefore, namely to restrict the flow of solvent from the measuring flask 30 to the burette 42 to a degree substantially less than the flow of solvent from the burette through the catheter 56.

The third leg of the T-coupling is connected to one end of the infeed tube 48, the opposite end of which is connected to a three way valve 78. The discharge tube 52 and the catheter tube 54 also are connected to this valve.

The valve is operable in one position of adjustment to interconnect the tubes 48 and 54 for introducing solvent to the renal pelvis. In a second position of adjustment of the valve the tube 54 is closed from both of the tubes 48 and 52, and the latter tubes are closed from each other. In a third position of adjustment of the valve the tube 54 is connected to the discharge tube 52 for draining the solvent from the renal pelvis.

The valve 78 may be of the manually operable type, preferably capable of manipulation by the patient, or it may be of the type operated by a mechanical or electrical control device on a predetermined time sequence in accordance with the method and mode of operation of the present invention.

The method and apparatus described hereinbefore offer many advantages, among which are the following: The single ureteral catheter may be of a larger size and still be insertable under circumstances wherein a plurality of smaller catheters may be difficult or impossible to insert. The single larger catheter is more easily maintained in place, detritis can escape more easily through it, and it is much less likely to become plugged. If it does become plugged to discharge, infeed to the renal pelvis is automatically stopped. Since low infeed pressure is employed and the volume of solvent introduced to the renal pelvis on each cycle does not substantially exceed the intrarenal capacity, there is no intrarenal pressure pain and the chance of trauma to the urothelium, extravasation and absorption of toxic matter is considerably decreased. The repeated emptying of the renal collecting system avoids the constant renal pelvic residual pool and attendant possibility of bacterial growth occurring in it, as characterized by the continuous flow method. The continuous back pressure against the renal filtration system, and consequent extended interference of function, resulting from the continuous flow method, is prevented, as is intrarenal pressure ischemia which results from continuous increased intrarenal pressure. The low intrarenal pressures employed in the present invention decrease traumatic hemorrhage and serous oozing, thus decreasing the possibility of formation of coherent detritus masses and catheter plugging. Calculi in the infundibuli and minor calyces are exposed more to fresh solvent than by the continuous flow method.

It will be apparent to those skilled in the art that variations may be made in the method and structural features of the apparatus described hereinbefore without departing from the spirit of this invention and the scope of the appended claims.

Having now described my invention and the manner in which it may be used, what I claim as new and desire to secure by Letters Patent is:

1. The method of dissolving renal calculi, comprising
(a) preparing a volume of calculus solvent predetermined not to substantially exceed the capacity of the renal pelvis cavity to be treated,
(b) introducing said predetermined volumes of solvent into the renal pelvis cavity,
(c) retaining said solvent in the renal pelvis cavity for a period of time sufficient to effect at least partial dissolution of the calculi,
(d) simultaneously with said retention period preparing another of said predetermined volumes of solvent for subsequent introduction into the renal pelvis cavity,
(e) removing the first named volume of solvent from the renal pelvis cavity, and
(f) repeating the steps of introducing, retaining, preparing and removing subsequent batches of said predetermined volume of solvent until the desired calculi dissolution is effected.

2. Apparatus for dissolving renal calculi, comprising
(a) a calculus solvent measuring container adapted to receive calculus solvent from a source of supply,
(b) level control means associated with the measuring container for maintaining solvent in the latter at a predetermined level,
(c) a calculus solvent dispensing container,
(d) first conduit means interconnecting the measuring container and dispensing container for delivering solvent from the measuring container to the dispensing container,
(e) means supporting the measuring and dispensing containers for relative vertical adjustment for adjusting the height to which the dispensing container is to be filled with solvent, which height provides in the dispensing container a volume of solvent predetermined not to substantially exceed the capacity of a renal pelvis cavity to be treated,
(f) a ureteral catheter,
(g) second conduit means interconnecting the dispensing container and the catheter for delivering said predetermined volume of solvent in the dispensing container to the renal pelvis cavity to be treated,
(h) flow restricting means associated with the first conduit means for restricting the flow of solvent from the measuring container to the dispensing container to a magnitude substantially less than the flow of solvent from the dispensing container to the catheter,
(i) drain conduit means communicating with the catheter for draining solvent from the renal pelvis cavity, and
(j) control valve means in the second conduit means and drain conduit means for selectively opening and closing said conduit means,
(k) the control valve means in the second conduit means functioning in one position of adjustment to open the second conduit means to discharge the contents of the dispensing container into the renal pelvis cavity and in a second position of adjustment to close said second conduit means and permit filling of the emptied dispensing container with solvent from the measuring container automatically to said predetermined volume.

3. The apparatus of claim 2 wherein the control valve means are manually operable and are positioned adjacent the catheter for manual operation by a patient being treated.

4. The apparatus of claim 3 wherein the ureteral catheter has a single lumen which communicates with both of the second conduit means and drain conduit means.

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