SINGLE NEEDLE DIALYSIS

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Access to the bloodstream is a problem in chronic hemodialysis. The presently preferred method is via dilated forearm veins which result from a surgically created arteriovenous fistula as described by Brescia and co-workers in 1966. Two venipunctures, or more in the case of a poor puncture, are required for dialysis. Since large needles are necessary, their insertion requires skill, is painful, and is detrimental to the fistula vessels. Usually, insertion of the second needle is considerably more difficult than the first. Therefore, if only one venipuncture were necessary, it would ease some of the problems.

It is possible to obtain sufficient blood for effective hemodialysis through a single lumen cannula by creating a tidal inflow and outflow alternating at short, regular intervals (Figure 1). Obviously the rate of tidal flow through a single cannula would have to be double that with 2 needles. Flow from fistula veins, even when 2 needles are used, is often less than desired. Factors which have been implicated as reasons for this include: a. small interior diameter of the needles, and b. poor flow within the fistula vessel.

Fourteen gauge fistula needles were found to give blood flow rates greater than 400 ml/min in vitro without excessive pressure. Secondly, flow rates through well developed subcutaneous fistulae are usually above 300 ml/min. On the assumption that valve-like interaction between the vessel wall and the bevel of the needle could be at fault, we designed a needle with lateral perforations near the tip. It has eliminated most of the flow problems encountered in double needle dialysis and also provides the flow rates required for tidal flow in single needle dialysis* (Figure 2).

Principle of operation. The inflow and outflow lines of the dialyzer are connected to the cannula by a Y-connector. The only dead space is in the cannula itself and its hub. Fresh blood is drawn into the inflow line by the blood pump while the venous return line is simultaneously occluded by a solenoid clamp. Alternately the inflow line is occluded and the clamp on the outflow line is opened, allowing the return of blood from the dialyzer to the patient. Repetition of this cycle results in a pulsatile, unidirectional flow of blood through the dialyzer (Figure 3).

The clamps+ are located ahead of the blood pump on the inflow side and below the drop chamber on the outflow side (Figure 4). The clamping cycle is controlled by pressure changes in the dialyzer circuit. These are detected by a special pressure monitor+ connected to the venous drip chamber (Figure 5). During the inflow phase, when the arterial clamp is open, the pressure in the dialyzer rises to a predetermined set point. Then the position of the clamps is reversed. As the blood returns to the patient, the pressure falls. After a brief interval, the clamps switch back and the cycle is repeated. The pressure at which the clamping cycle is controlled is automatically maintained. Ultrafiltration and the clamping cycle are combined in the automatic control. The set point is manually adjustable to any desired point between 0 and 300 mm Hg. There is no need for a screw clamp on the venous bloodline. The frequency of the cycles is regulated by an adjustable timing switch. This determines the duration of the interval during which the venous clamp is open. By this means, the volume of blood exchanged at each cycle can be adapted to any given pump speed. Table I indicates the range which has been found practical in clinical use.

TABLE I

TIDAL VOLUMES

seconds delay	bloodflow (ml/min.) 100	150	200	250	300	cycles/ minute
0.5	1.7	2.5	3.3	4.2	5	60
0.6	2.0	3.0	4.0	5.0	6	50
0.7	2.3	3.5	4.6	5.4	7	43
0.8	2.6	4.0	5.3	6.7	8	38
0.9	3.0	4.5	6.0	7.6	9	33
1.0	3.3	5.0	6.7	8.4	10	30

Clinical Range indicated in block

The system is self-regulating. Feedback from the pressure sensors determines the tidal blood volume. Any impediment of blood flow will alter the rhythm of the clamping cycle. It will stop if there is no flow from the vessel. Thus, any flow problem is indicated by an audible irregularity and can be promptly checked. The monitor provides safety limits for high or low pressures. It can also be used as a regular high-low safety monitor for standard double-needle or shunt dialysis. The blood pump is stopped and an alarm is sounded.

Recirculation. There is some recirculation of blood due to back-mixing at the Y-connector. Angiographic studies were done to visualize the flow pattern in the blood vessel and the needle site (Figure 6). Dye was injected into the outflow line from the dialyzer. As it left the fistula needle, it was immediately carried away by the bloodstream. No dye was drawn back at

*Manufacturer: Deseret Pharmaceuticals, Sandy, Utah.
+Manufacturer: Vital Assists, Inc., Salt Lake City, Utah.

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the next inflow phase, indicating that very little blood is sucked back after it has left the needle. The amount of recirculated blood is mainly due to the dead space at the Y and the cannula. Direct measurement shows that the dead space is 0.6 ml with the Angiocath-type cannula, where the Y is part of the needle.

The proportion of mixing has been determined by hematocrit dilution studies (Figure 7). At the beginning of dialysis, saline returns from the dialyzer to the patient, while the patient's blood fills the inflow line. Small boli of saline are mixed with the inflowing blood according to the degree of recirculation. The hematocrit of blood contained in the arterial flow chamber therefore shows the dilutional effect when compared with the patient's hematocrit. Recirculation rarely exceeded 20% of total flow. With good flow conditions, the average was lower - around 10%.

The dilutional effect by previously dialyzed blood on the concentration of any given substance in the inflow to the dialyzer can be calculated according to the rate of clearance for the substance. It was found that for a substance with a clearance of 70% in the venous blood, the concentration in the inflow line would be reduced by 7% with a 10% mixing fraction.

Example. Concentration of blood from the fistula: 100%
Concentration of blood from the outflow line: 30% (= 70% clearance)
a) percent mixing at the Y: 10%
b) x = concentration of diluted blood in the inflow line to the dialyzer.
Therefore:

(9 parts of 100% + 1 part of 30% = 10 parts of x%, $9 \times 100 + 1 \times 30 = 10x$, $x = 93\%$).

Even with a large membrane surface, 70% clearance is rarely achieved for molecules larger than urea. It is probable that the influence of back-mixing on the removal of metabolites other than urea is negligible. Indeed, this dilution effect may be beneficial because it will reduce the clearance of smaller molecules during the initial hours of treatment, when their extraction would otherwise be highest. The removal of substances of high osmotic effect is therefore delayed and continues in a more even manner throughout dialysis. Subjectively, patients report fewer headaches, cramps, and other symptoms.

Hemolysis. Mechanical trauma to the erythrocytes does not seem to be increased by the action of the clamps or by the tidal flow through one cannula. Calculation of shear-stress values indicates that hemolysis is unlikely to occur as a result of conditions peculiar to the single needle system. Shear stresses in standard systems were found to be 100 times higher at the site of the screw-clamp used to regulate ultrafiltration. However, damage may result from the action of the blood pump if it is not properly adjusted. It should not be allowed to operate with collapsed tubing segments. Correct occlusion is also mandatory.

Eighty-five plasma hemoglobin determinations were done. Equal incidence of elevation was found in pre- and post-dialysis specimens from single needle patients, patients with external shunts, and standard double needle dialyses.

Modifications of single needle dialysis. A number of modifications are conceivable by which tidal flow through a one lumen cannula might be achieved. The present system with a double clamp which alternately occludes the inflow and outflow lines has proven to be most useful. It can be adapted to the various kinds of dialyzers - coil, Kiil, hollow-fiber, and others.

Intermittent operation of the blood pump in a pattern of stop-go-stop-go may also be used to occlude the inflow line alternating with the action of a single venous clamp. This version was extensively used during the initial trials.

Recirculation is a necessary feature of another version, in which only one clamp on either the inflow or the outflow line is used. The pump speed has to be double the flow rate between the patient and the dialyzer circuit. This system cannot be used with dialyzers which have high internal resistance, because ultrafiltration becomes excessive.

Pressure sensing. The location of the pressure monitor in the dialyzer circuit is a matter of great practical importance. The venous drip-chamber - a normal component in most tubing sets - has proven quite satisfactory. In principle, any point in the dialyzer circuit may be used. We prefer blood tubing sets which also include an arterial flow chamber. The air above the blood level provides ideal compliance and dampening of the amplitude of the pressure changes in the inflow line. A negative pressure gauge may be applied at this point to control suction. It should not exceed minus 250 mm Hg.

Pressure regulated systems have the advantage of incorporating several safety features automatically. They also maximize flow because their function depends on proper blood exchange as evidenced by the pressure changes. According to which phase the time-delay is applied, the clamping cycle may be controlled by 2 different modes: a) rising pressure, or b) falling pressure. Independent timing devices have also been used to control the alternate occlusion of the bloodlines. However, such a system lacks the important features of self-regulation and feed-back between pressure and flow(1). At this time they cannot be considered practical or safe.

CLINICAL EXPERIENCE AND RESULTS

Clinical trials were begun in December, 1970. The patient who has been maintained longest on single needle dialysis began in January, 1971. He is on dialysis at home now with this method. To the present time a total of about 600 dialyses have been performed. Eleven patients have been trained successfully for home dialysis and placed in their homes with the single needle system. The longest has used it since August, 1971. These patients dialyze 3 times/week, 5-6 hr/run, using the EXO3® Coil. Extension of dialysis time has not been necessary as compared with times which were optimal for double needle dialysis. Dialysis times have always been determined using the "Total Flowmeter"(2). Blood flow rates have been kept between 150 and 200 ml/min. Pre-dialysis levels of BUN, creatinine, and other metabolites are in the same range as with conventional dialysis (Figures 8-10). All patients show rising hematocrits and are well rehabilitated, except for one whose peripheral neuropathy was present before starting regular dialysis. No increase in dialyzer leaks has been encountered. The method has been tried with all types of dialyzers - coil, Kiil, hollow-fiber, and others - without difficulties.

Although single needle dialysis was intended for well-developed fistulae, it has shown considerable merit in patients who - but for one small segment of a fistula vessel - had completely run out of shunt sites. Such patients have been maintained with the method without undue difficulty using the small segment, or via femoral vein, until a better fistula could be constructed. Other vessles, such as the femoral vein, subclavian vein, or a large brachial vein, can be used, particularly if only a few dialyses are needed, as in acute cases. It is not advisable to use arterial puncture because of the high pressure which interferes with the return of the blood from the dialyzer.

The reduced number of venipunctures is of course beneficial for the fistula vessels. The best dilated segment can be selected for venipuncture, also assuring optimal flow rate. In several patients, venipunctures have been performed without a single failure for weeks or months. The average hook-up and insertion time has been significantly shortened. Mutilation and scarring of the puncture sites is minimal.

SUMMARY

The single needle method is simple, effective, and safe. No disadvantages have become apparent. The method has been successfully applied to acute and chronic dialysis on a long term basis in the center and in the home. Patients and personnel have accepted it very favorably. It has greatly facilitated blood access via A-V fistulae. Fistula-dialysis may be made significantly less arduous by this development.

ACKNOWLEDGMENT

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2. Kopp, K. F., Gutch, C. F., and Kolff, W. J. The liter-kilogram-concept in prescription and evaluation of hemodialysis. Proc. Clin. Dialysis Transpl. Forum, 1:31, 1971.

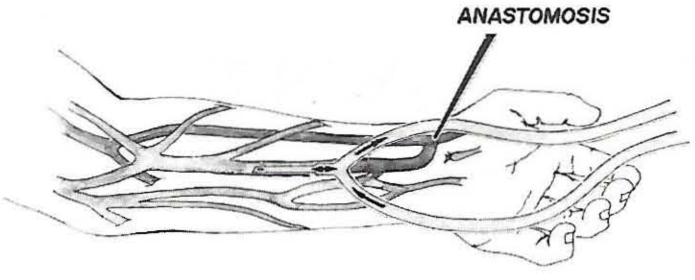

Figure 1. Tidal flow through a single lumen cannula.

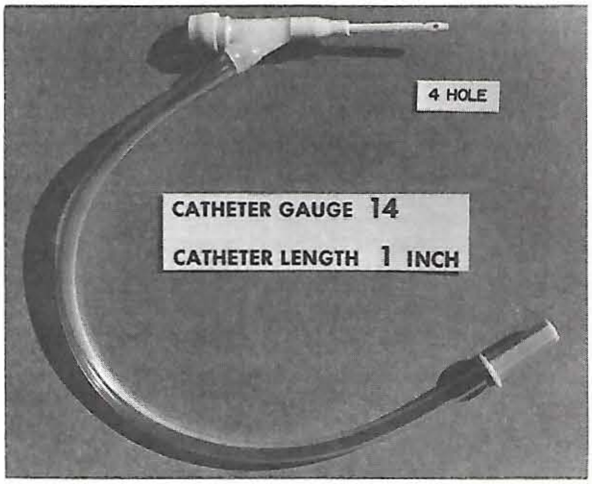

Figure 2. Teflon-cannula with lateral perforations near the tip. Note Y-Connector.

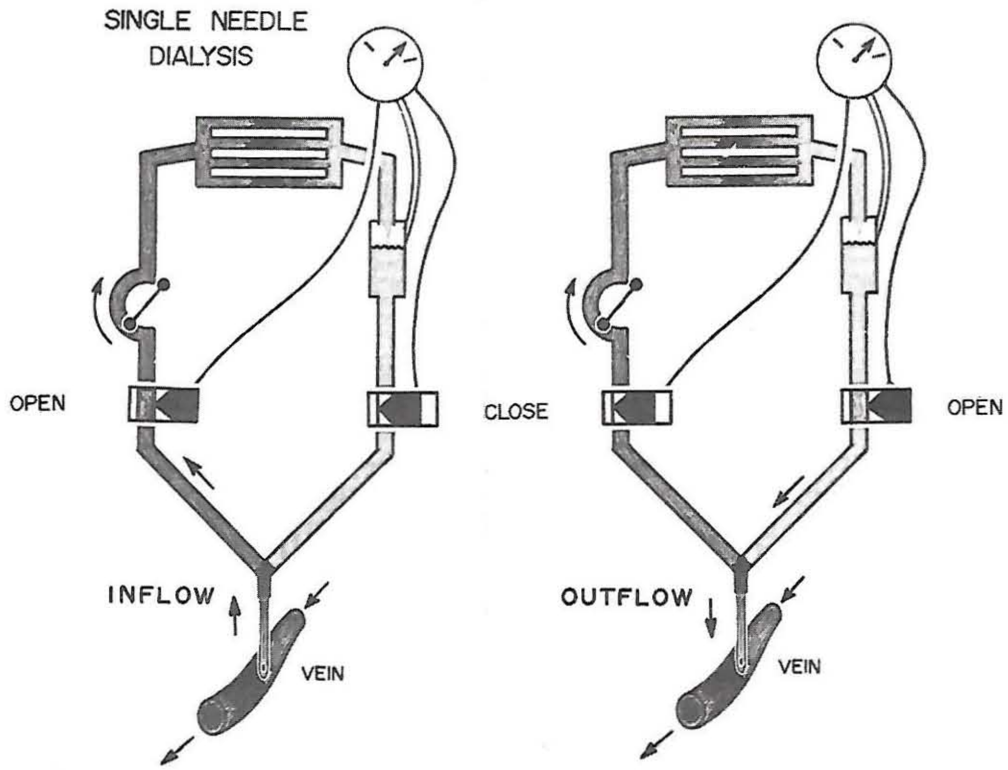

Figure 3. Diagram showing clamping cycle and blood flow in single needle system.

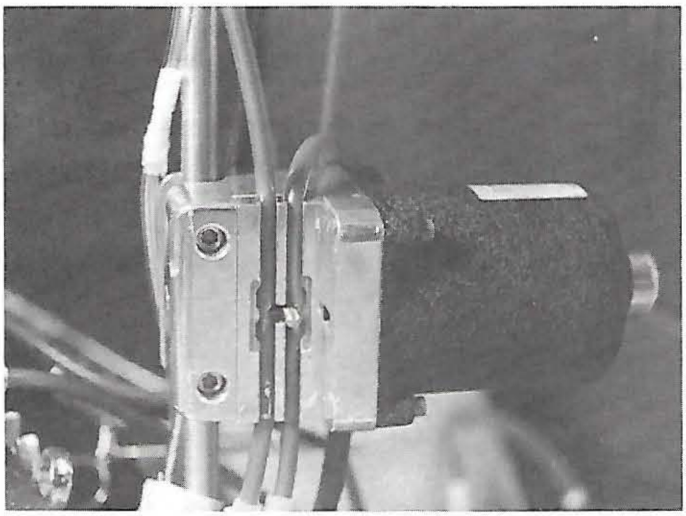

Figure 4. Double solenoid clamp for alternating occlusion of inflow and outflow line.

Figure 5. Single-needle pressure monitor.

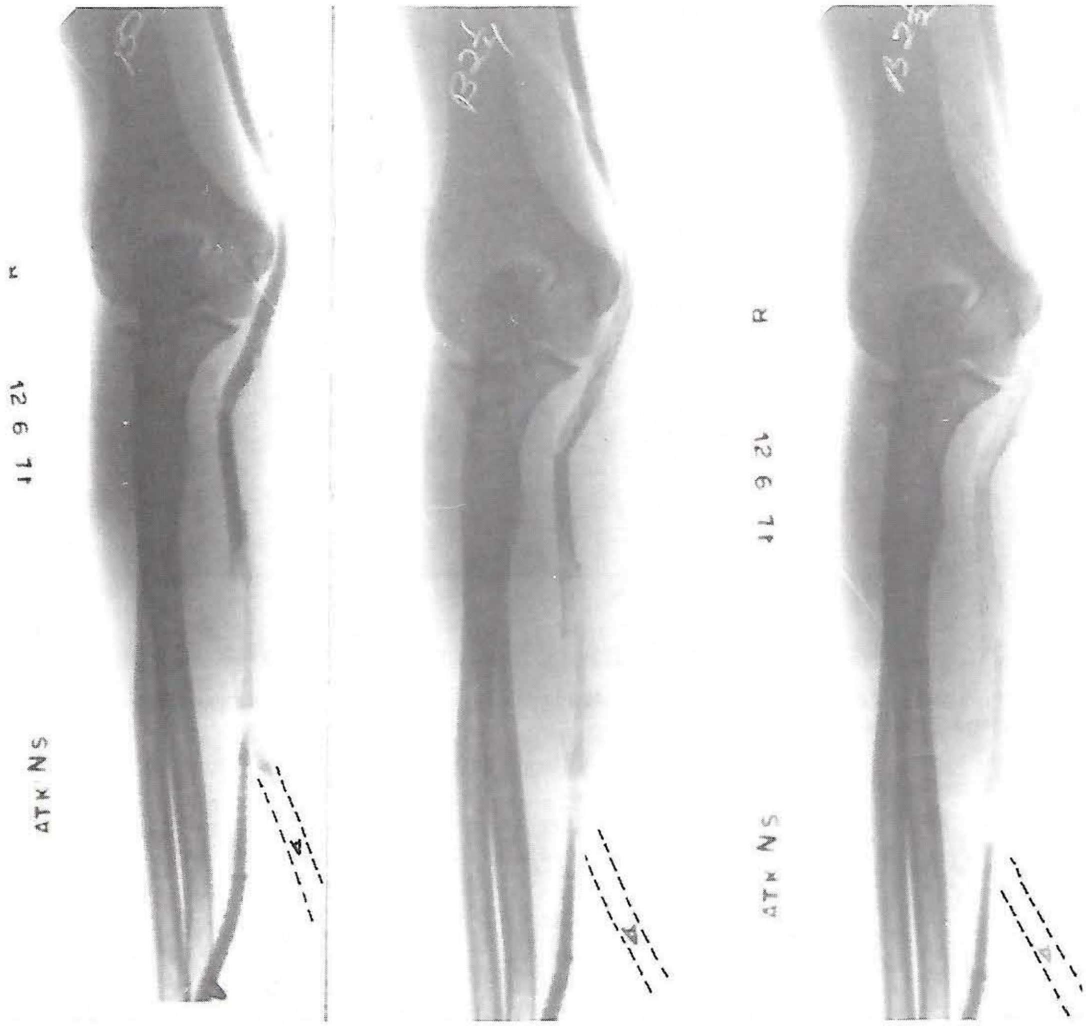

Figure 6. Angiogram showing one full cycle of tidal flow. No dye is seen in the inflow line (A).

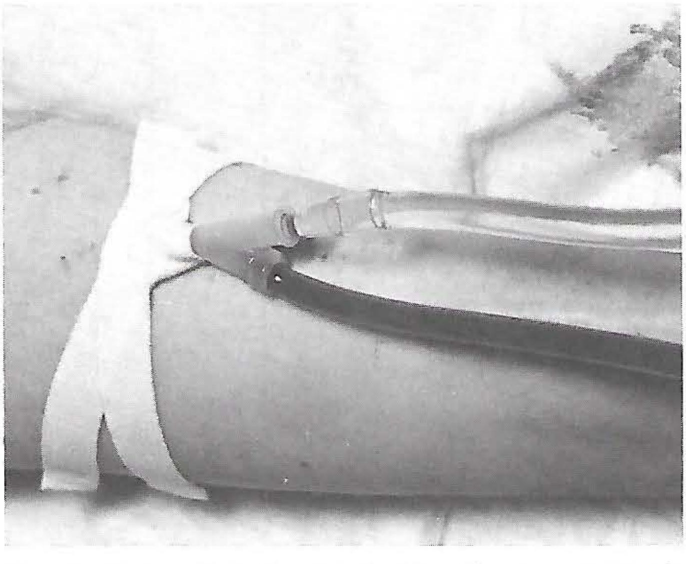

Figure 7. Single needle in site. Note blood in outflow line, saline in inflow line.

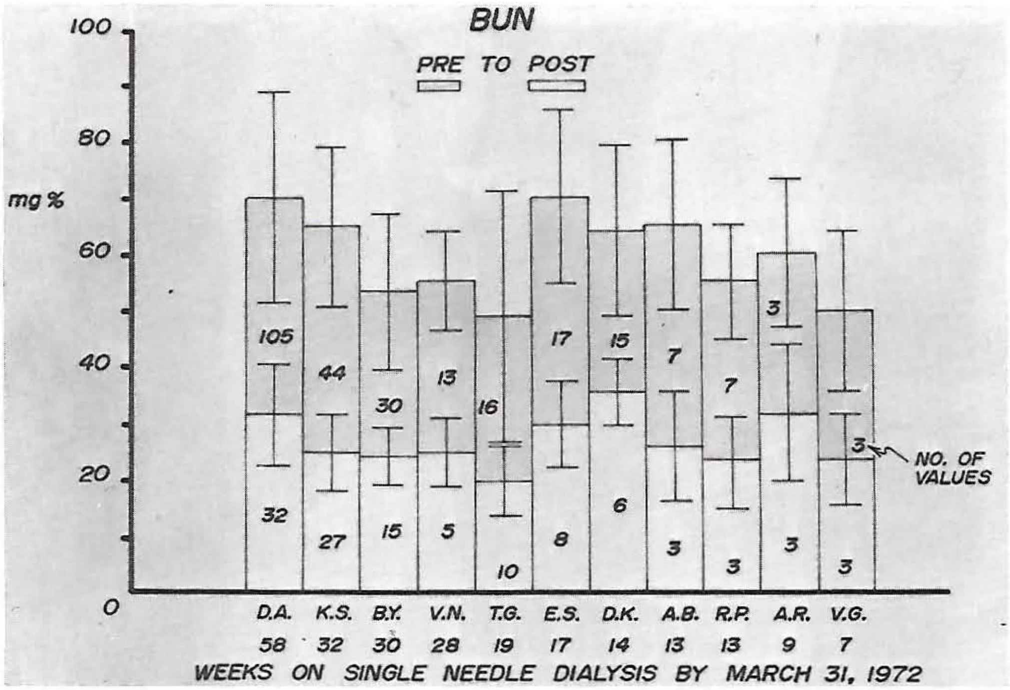

Figure 8. Means and standard deviations of BUN values before and after dialysis. All 11 patients are now on home dialysis.

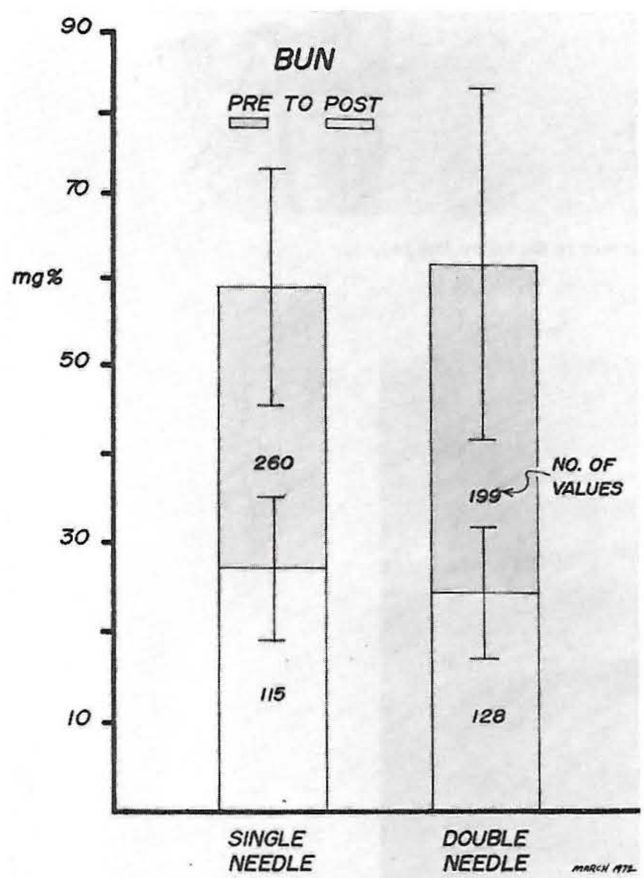

Figure 9. Means and standard deviations of BUN values before and after dialysis comparing single needle and double needle dialysis.

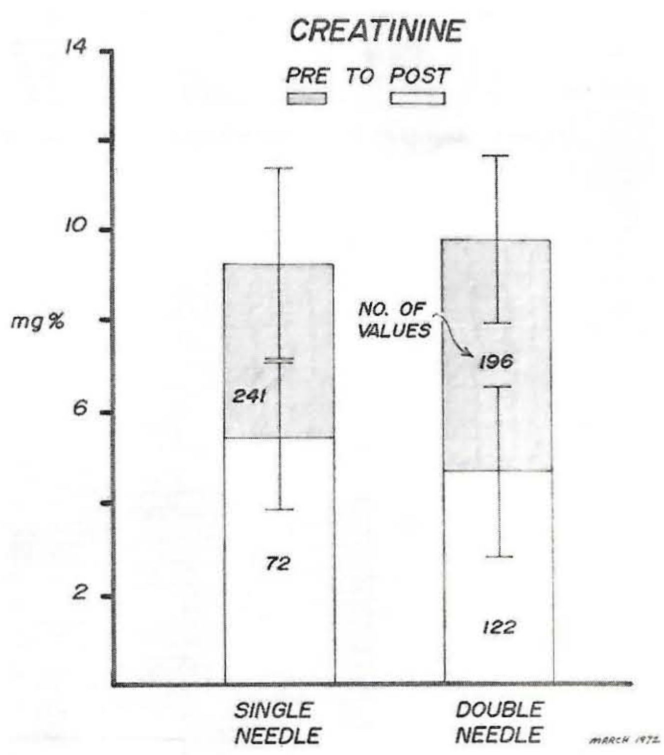

Figure 10. Means and standard deviations of creatinine values before and after dialysis comparing single needle and double needle dialysis.