Introduction

Postoperative hyponatremia is a common clinical occurrence in the United States with an occurrence rate of 1 to 5 percent. In the United States, the projected mortality and morbidity rate for postoperative patients with hyponatremia is more than 10,000 cases per year. (Based on 25 million surgeries per year, and an incidence of hyponatremia of 1 percent or 250,000 cases.) The frequency of hyponatremic encephalopathy among postoperative patients was 8 percent or a projected 20,000 cases per year. For patients with hyponatremic encephalopathy, the morbidity rate was 52 percent. 1

Brain injury in hyponatremic patients results from at least two distinct mechanisms. The first mechanism is hyponatremic encephalopathy, brain swelling and increased intracranial pressure resulting from the condition itself. Hyponatremic encephalopathy is not associated with treatment for hyponatremia since this brain damage occurs in untreated patients. 2

The second mechanism is associated with improper treatment for hyponatremia, defined as an increase of more than 25 mmol per liter in the initial 48 hours. 3

“Brain myelinolysis (pontine and extrapontine demyelination) clearly follows inappropriate, excessive correction of chronic and sometimes acute hyponatremia.” 4

“Optimal management of hyponatremic patients involves weighing the risk for illness and death from untreated hyponatremia against the risk of myelinolysis due to correction of hyponatremia.” 5

Controversies

The treatment of hyponatremia has been a fairly controversial topic for a number of years. As stated in an editorial in the *Annals of Internal Medicine*, “Few subjects consistently engender as much heated discussion as the treatment of hyponatremia. Whereas some authors emphasize the catastrophic consequences associated with the failure to treat the symptomatic patient with this disorder, others point to the equally catastrophic outcome that can accompany treatment.” 6

Further fueling this debate are the mountains of research literature on the topic. A Medline search under the topic of “hyponatremia,” narrowed from articles published from 1995 to 2002, resulted in more than 800 articles. Even a brief sampling of this medical literature reveals the depth of the controversy.

Several studies have shown that although hyponatremic encephalopathy can occur in anyone, the occurrence of brain damage and death demonstrates a clear disposition in women. The age and gender of a patient are major determinants of brain damage...
from hyponatremia. 7 Research published in the Annals of Internal Medicine further explored this gender and age link, finding that menstruant women with hyponatremic encephalopathy are significantly more likely to experience permanent brain damage or death than are either men or post-menopausal women. 8 However, other clinical studies have failed to demonstrate a higher female disposition for hyponatremia or its complications. 9

Considerable discussion has taken place about how quickly to increase the sodium serum concentration levels for patients with hyponatremia. Most commonly, “rapid correction” is considered to be more than 25 mmol per liter in 48 hours. However, this figure varies in the literature from 10 to 14 mmol per liter in 24 hours. “Thus, although the data from clinical studies and studies in animals indicate a low incidence of myelinolysis if the increase in serum sodium is 12 mmol per liter or less in 24 hours, it may be impossible to define a level of correction that is always completely free of risk.” 10

As the debate continues in the literature about the appropriate treatment for hyponatremia, there are a few steps physicians can take to practice safe medicine and protect themselves from allegations of malpractice in this area of treatment. Stay informed and review current literature. Always request appropriate consults when deciding the best course of treatment for hyponatremia. In spite of the gravity of this clinical condition, there is no consensus about the optimal therapeutic approach and this presents a dilemma for the physician who may encounter it rarely in a career. There is no debate that the rate of correction must be monitored frequently with sodium levels to verify the change is proceeding at the desired rate. This approach provides a prudent balance and avoids overzealous therapeutic intervention.

Sources
The following closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician’s defensibility. An attempt has been made to make the material less easy to identify. If you recognize your own case, please be assured it is presented solely for the purpose of emphasizing the issues of the case.

Clinical presentation

A 32-year-old woman presented to the emergency room complaining of flank pain and bloody urine. The patient had a history of von Willebrand’s disease, kidney stones, hysterectomy and multiple drug allergies. The ER physician diagnosed ureteral stone immediately after the surgery and eight hours later. The patient received another 20 mcg IV infusion of DDAVP in 15 cc NS three times the following day.

Following the procedure, the patient developed persistent bleeding with abdominal pain and a decrease in urine output. The urologist decided to perform the stone removal procedure the next day, earlier than originally planned. On the day of the second surgery, the patient’s Na level was 121, a significant decrease from 143 on admission, K+ 3.34. There was no written order in the chart for the basic metabolic panel which revealed the 121 sodium level, and there was later testimony that this lab report was not in the chart the day after the surgery. The urologist was not aware of the existence of this lab report. The patient was given 20 mcg DDAVP in 15 cc NS, and was taken to surgery. The procedure was performed without complication. The urologist’s post-operative orders omitted DDAVP, but the medical record showed a “P.O.” handwritten in the chart to resume DDAVP at previous order. Based on that order, the patient continued to receive DDAVP at eight-hour intervals.

Over the next two days, the patient developed nausea and became weak and confused. The urologist ordered an internal medicine consult. The internal medicine physician noted the DDAVP doses were too high and should be in doses of 15 mcg over 15 minutes in 50 cc NS. He ordered a re-check of the patient’s basic metabolic panel, which revealed a Na level of 107, K+ 3.1. The internist ordered 3 percent saline at 60 cc/hr IV x 800 cc only, and electrolyte checks every four hours. When the sodium reached 120, the nurses were to stop the hypertonic saline and go back to NS with 40 meq KCL at 75 cc/hr.

Hypertonic saline was started, and the four-hour lab draws showed sodium at 106 and 111, respectively. The patient was again seen by the internal medicine physician who continued the hypertonic saline and discontinued the DDAVP. The 0900 labs showed Na at 124, K+ 2.9. An hour later, the hypertonic saline was discontinued and 0.9 NS with 40 meq KCL at 50 cc/hr was ordered. A lab draw three hours later showed Na at 131, K+ 3.6. The patient reported to the nurse that she was unsteady on her feet and was unable to spell.

Later that morning, the internal medicine physician ordered the patient’s IV fluids to one-half NS with 40 mcq KCL at 50 cc/hr. Lab values three hours later showed Na of 134, K+ 3.1 and the patient was noted to be confused and forgetful. The following day, the patient’s Na was at 130, K+ 3.34, and the internal medicine physician and the urologist felt the patient was stabilizing. The four-hour lab draws were discontinued, and the patient was later allowed to eat by mouth. The IV was discontinued. Three hours later, however, the patient began having difficulty speaking and remembering words. She developed right facial droop and right arm numbness.

The patient was seen by a neurologist who suspected neuronal swelling or central pontine myelinolysis. An MRI was ordered and the patient was transferred to ICU. The MRI showed “bilateral symmetrical findings in the basal ganglia region, possibly secondary to osmotic extrapontine myelinolysis.” Despite attempts to restart DDAVP and alter intravenous fluids to correct electrolytes, the patient’s status rapidly declined. She remained hospitalized for several months and underwent another several months of rehabilitation. She is currently living with her parents and has permanent, profound impairment of her mental and neurological status.

Physician action

The following day, the patient was seen by the on-call urologist, one of the defendants in this case. He diagnosed left mid-urethral calcification with bleeding disorder. His treatment plan included placing a urethral stent after administering DDAVP. He would follow up with a staged ureteroscopy 1 to 2 weeks later to remove the stone.

The urologist contacted the patient’s hematologist to discuss the use of DDAVP. The hematologist indicated the patient had been given DDAVP in the operative setting previously with no complications. The hematologist reportedly advised that the patient should be given 20 mcg in 15cc NS 30 minutes prior to surgery and every 8 hours for up to 48 hours following surgery.

The patient was given 20 mcg DDAVP before the procedure, and the stent was placed without complication. Following the urologist’s post-operative orders, the patient was given DDAVP, 20 mcg in 15 cc NS immediately after the surgery and eight hours later. The patient received another 20 mcg IV infusion of DDAVP in 15 cc NS three times the following day.

Continued on page 4
Legal implications
Causation was an important factor in the defense of this case. The defense was able to locate expert testimony indicating the patient’s neurologic injury was due to the rapid correction of her hyponatremia, rather than the hyponatremia itself. The patient’s sodium level went from 106 to 134 in approximately 20 hours. However, defense consultants found that the urologist fell below the standard of care in:

- failing to obtain a formal hematology consultation or coagulation studies before attempting to treat von Willebrand’s disease
- prescribing DDAVP in a dose in excess of that recommended by the PDR
- failing to recognize the potential for hyponatremia as a consequence of DDAVP combined with fluid administration
- failing to appropriately order monitoring of electrolyte levels
- proceeding with surgery without recognizing a documented, depressed sodium level

Also important to note in this case was the confusion and inconsistency regarding the medical record. The urologist testified he did not order the metabolic panel that showed the sodium level of 121, and that he was never informed of the sodium level. He further stated he would not have performed the second surgery if he had been informed of the sodium level. Following the second surgery, the urologist’s post-op orders that indicate which medications to restart do not list DDAVP. However, there is an addendum in the medical record that indicates a nurse spoke with the urologist by telephone and was told to resume the DDAVP. The urologist does not recall this phone call, but says the nurses may have called to discuss the “blanket issue” of whether to re-institute all previous medications. The issue of who ordered the continuation of the DDAVP became a hotly debated topic between the nurse and the physician.

Even with the causation testimony, it was felt that defending the high doses and extended duration of DDAVP, combined with the lack of electrolyte monitoring, would be difficult. The plaintiff, a young woman with two small children, suffered profound and permanent injury and would have made an extremely sympathetic witness to a jury.

Disposition
This case was settled on behalf of the urologist for $500,000. Legal expenses in the defense of this case totaled more than $110,000. Two other defendants in this case reached settlements totaling $1.45 million and $110,000. Two other defendants in this case

Risk management considerations
Retrospectively, a review of this patient’s care provokes several concerns. With the known history of von Willebrand’s disease, an unusual condition infrequently encountered by many physicians, a consult with hematology or internal medicine before proceeding with procedures would have facilitated better management of DDAVP and intravenous fluids. Likewise, the patient should have been closely monitored during the post operative period by the consultant. Knowing complete patient history and requesting preoperative clearance to ensure the best management of pre-existing conditions reflects the standard of care.

In this case three internal medicine physicians were involved in this patient’s care based on who was on duty or on call. Managing the sodium level along with intravenous fluids crossed over shift and call responsibilities. One physician gave orders for sodium levels every four hours and requested notice if the level increased more than 1 meq/hr. The level increased 5 meq in three hours and internal medicine was notified but it was a different physician at 3:50 a.m. The orders were not changed.

Several issues of concern are noted. Did these physicians communicate regarding this patient in a comprehensive manner? How can patient care be effectively managed under such challenging circumstances when three physicians are involved in less than 24 hours?

Did these physicians have current knowledge regarding the management of hyponatremia? A physician reviewing the case explained the sodium level was corrected too rapidly, more than double that recommended by experts in the field. This physician opined a more cautious approach with discontinuation of the DDAVP and restriction of fluid intake to 2/3 of the patient’s daily maintenance. Once the patient was found to be acutely hyponatremic, this should have been recognized as a critical problem, requiring close monitoring in the intensive care unit with a nephrology consultant notified immediately. The management of acute hyponatremia, as opposed to chronic hyponatremia, is extremely difficult and challenging, requiring the knowledge and skills of an expert.

Good communication among multiple physicians and hospital staff involved in the care of a patient is essential. The timely, accurate and comprehensive documentation of all orders and discussions relevant to that patient’s care is necessary for optimal patient outcomes.
Protecting your assets from lawsuits

By Ken H. Vanway, P.C., attorney at law

The Reporter will feature a bimonthly column to answer your most frequently asked questions about asset protection. We invite you to email or write Ken Vanway with your questions, ken@vanway.com or Law Office of Ken H. Vanway, P.C., First Commercial Bank, 1110 RR 620 South, Suite B, Austin, Texas 78734.

The information provided in this article is not to be construed as legal advice and should not be relied upon without specific consultation with a professional.

Asset protection with separate property agreements

General rule in Texas — if you are married and reside in Texas, everything is equally owned 50/50 unless you can prove otherwise. This is because Texas is one of only 8 community property (CP) states in the United States. The other CP states are Arizona, California, Idaho, Louisiana, Nevada, New Mexico and Washington. The basic premise of the community property system is that each spouse in the marriage has an equal one-half interest in the property accumulated as the result of the efforts of either during the marriage. Therefore, CP is the default form of property ownership in Texas.

Where did this concept of community property originate?
The concept of community property has its roots in our Spanish heritage, which explains why most of the CP States are located in the Southwest. CP was originally a means of protecting the family (i.e. the “community”). CP also enjoys favorable income tax advantages under the tax code in that when one spouse dies, the surviving spouse receives a new, increased cost-basis equal to the market value of the assets as of the date of death. This can result in the elimination of capital gains taxes to a surviving spouse.

Is CP ownership a problem in a lawsuit?
Yes. The drawback to community property in the context of asset protection estate planning is that what is considered “ours” is also considered “theirs.” If one of the spouses is sued by a creditor the community assets are subject to attachment or seizure. When a malpractice judgment is rendered against the physician-spouse, the judgment creditor can seize and attach the following assets: the physician-spouse’s community assets. Therefore, if the CP income is left to commingle with the SP asset, the CP asset can be tainted and converted into CP which makes the entire asset subject to seizure from a lawsuit judgment.

In asset protection estate planning, this concept of asset titling is very important in creating an estate plan, for funding various trusts or creating partnerships, equalizing estates for tax purposes and in the concept of protecting the estate in general.

What is a Separate Property Agreement?
A SP agreement is merely a contract between husband and wife that decides how the spouses wish to hold title to assets (i.e. CP or SP). This agreement can cover both existing assets as well as future assets or income, salary, etc. It is now possible in Texas to have a marriage without any community property. Many times the agreement will also contain other provisions such as buy-out provisions in the event of divorce or dissolution of the marriage.

Can the agreement be changed or terminated later?
Yes. The agreement is very flexible. It can either be amended or terminated. It only requires the written consent of both spouses. We draft our agreements to provide property exhibits so that the exhibits can be easily changed in the future without the need to change the entire agreement.

How will this affect my income tax?
No effect. You can continue to file joint or separate returns as you desire.

Is there a gift tax problem in transferring assets between spouses?
No. The tax code provides for unlimited transfers between a husband and wife without gift tax.

Does the division of assets between spouses have to be equal?
No. The division can be equal or unequal so long as the parties both agree; however, see below in the event of divorce.

What are the “downsides” of a separate property agreement?
If you get divorced, a divorce judge has no jurisdiction over separate property. Therefore, if there continued on page 8
Hormone replacement therapy

by Scott Allen and Jay Henderson, attorneys at law, with the law firm of Cruse, Scott, Henderson and Allen

The following article was prepared by the lead attorneys in TMLT’s mass litigation defense team for your information on this timely issue. Web site addresses that will enable you to access the source studies and early commentary on hormone replacement therapy have been provided in this article. We hope the information we are passing along is helpful to you.

National Heart, Lung, and Blood Institute

On July 9, 2002, the National Heart, Lung, and Blood Institute (NHLBI) announced the discontinuation of a major clinical trial of the risks and benefits of combined estrogen and progestin in healthy, menopausal women due to an increased risk of invasive breast cancer among study participants. This large, multi-center trial, which was a component of the Women’s Health Initiative (WHI), also found increases in coronary heart disease, stroke, and pulmonary embolism in study participants on estrogen plus progestin compared to women taking placebo pills. Although there were noteworthy benefits of estrogen plus progestin, including fewer cases of hip fractures and colon cancer, “on balance the harm was greater than the benefit.” The NHLBI press release may be reviewed in its entirety at the NIH web site: http://www.nih.gov/news/pr/jul2002/nhlbi-09.htm.

According to NHLBI Director Claude Lenfant, MD, a primary impetus for the WHI study was to determine whether postmenopausal hormone therapy prevents heart disease. “The bottom-line answer from WHI is that this combined form of hormone therapy is unlikely to benefit the heart. The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits — and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.”

JAMA Report

The results of the WHI study were published in the Journal of the American Medical Association on July 17, 2002. The complete report may be found at http://jama.ama-assn.org/issues/v288n3/ffull/joc21036.html. This article explains that the WHI is a long-term study that focuses on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in postmenopausal women. The study utilized combined estrogen and progestin (Prempro, Wyeth Ayerst) and a matching placebo. Formal monitoring began in the fall of 1997 with the expectation of final analysis in 2005, after an average of approximately 8.5 years of follow-up.

According to the investigators, “The trial was stopped early based on health risks that exceeded health benefits over an average follow-up of 5.2 years.” This action was taken after a meeting of the Data Safety and Monitoring Board (DSMB) in May 2002, which found that “the adverse effects in cardiovascular diseases persisted, although these results were still within the monitoring boundaries. However, the design-specified weighted log-rank test statistic for breast cancer . . . crossed the designated boundary . . . and the global index was supportive of a finding of overall harm.” The DSMB “concluded that the evidence for breast cancer harm, along with evidence for some increase in CHD, stroke, and PE, outweighed the evidence of benefit for fractures and possible benefit for colon cancer over the average 5.2 year follow-up period. Therefore, the DSMB recommended early stopping of the estrogen plus progestin component of the trial.”

In discussing the “overall risks and benefits” of the tested drug therapy, the JAMA authors concluded, “At the end of the trial, the global index indicated that there were more harmful than beneficial outcomes in the estrogen plus progestin group vs. the placebo group.” In discussing the findings in detail, the report states, “The absolute excess risk (or risk reduction) attributable to estrogen plus progestin was low. Combining all the monitored outcomes, women taking estrogen plus progestin might expect 19 more events per year per 10,000 women than women taking placebo. Over a longer period, more typical of the duration of treatment that would be needed to prevent chronic disease, the absolute numbers of excess outcomes would increase proportionately.” In conclusion, the authors remark, “The trial results indicate that treatment for up to 5.2 years is not beneficial overall and that there is early harm for CHD, continuing harm for stroke and VTE, and increasing harm for breast cancer with increasing duration of treatment. This risk-benefit profile is not consistent with the requirements for a viable intervention for the primary prevention of chronic diseases.”
JAMA editorial

Accompanying the JAMA report on the WHI is an editorial by Suzanne Fletcher, MD, MSc and Graham Colditz, MD, DrPH. These physicians observed that the WHI was the “first randomized primary prevention trial of postmenopausal hormones” and that the results of the WHI were “surprising.”

In their discussion on how practicing clinicians and millions of women taking an estrogen/progestin combination should react to this study, the authors note that “the absolute risk of harm to an individual woman is very small.” However, they conclude that “nevertheless, when counting all events over the 5.2 years of the trial, the excess number of events in the active drug group was 100 per 10,000 (or 1 in 100 women). This is still a small risk, but it demonstrates that risks from the drug add up over time.” Based upon these observations, these authors “recommend that clinicians stop prescribing this combination for long-term use.” The authors remark that protection against osteoporosis may be available through “alternative preventive strategies.” These authors additionally note that the WHI does not specifically address the short-term use of this drug therapy for managing menopausal symptoms. “The WHI trial does not specifically address this question, but the results suggest short-term (less than one year) of the combination has risks for coronary heart disease and thromboembolic disease. The possibility of these small absolute risks must be balanced against the severity of symptoms and benefit of treatment.” Still, the authors state, “The WHI provides an important health answer for generations of healthy, post menopausal women to come — do not use estrogen/progestin to prevent chronic disease.”

Commentary

The physicians and organizations quoted above do not say that there is never a use for the combination of estrogen and progestin for the short term in treating menopausal women. However, careful consideration and thorough informed consent outlining the potential risks and benefits of short-term use should be given when its use is contemplated. The physician is advised to document in writing this comprehensive informed consent, so that the communication of the potential risks and benefits of short-term estrogen-progestin therapy is memorialized.

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Federal HIPAA regulations apply to every physician office. If your practice has not begun compliance initiatives, the time to start is now. Please be aware of the following timelines.

**October 16, 2002** — Compliance deadline for Transaction Standards unless you have filed for the one year extension. Filing for an extension is advised by TMA and AMA for every office submitting electronic claims. Web site: www.cms.gov

**April 14, 2003** — Compliance deadline for Privacy Standards.

The final Security Standards are expected to be published in October 2002 with a compliance date in 2004.

Helpful web site: www.hipaadvisory.com

are concerns with a future divorce, then you would only want to make the division 50/50.

You only get the “stepped-up” basis upon death on any community property plus any separate property of the deceased spouse. You do not receive a new basis on the surviving spouse’s separate property.

**How effective are the agreements?**

It is critical that the parties recognize that a court has no jurisdiction over a person’s separate property in the event of divorce. It is also important to understand that a properly drafted and executed document entered into (1) voluntarily and (2) by fully informed parties with (3) full and complete disclosure is difficult to challenge in Texas. The agreements are, of course, amendable or revocable upon agreement of the parties. Merely destroying the document (you may be surprised how many clients try this) is insufficient to revoke the agreement.

**What if the “innocent-spouse” gets sued?**

In the event that the non-physician, innocent-spouse is the victim of a lawsuit judgment, then we have also preserved the separate property assets of the physician-spouse. The SP agreement is not a 100 percent solution but merely a first step towards an APEP. Coupled with other techniques such as family partnerships, children’s trusts, etc., complete protection can be had.

**How does a SP agreement work in conjunction with my Family Limited Partnership?**

A Texas FLP provides the maximum in asset protection on a domestic basis; however, if you have a malpractice judgment against you, with an FLP you still face the problem of the limitations of a “charging order” (CO). A CO allows the judgment creditor to seize any income that is distributed to the partner against whom the CO is assessed.

The SP agreement prevents the CO from being assessed against both spouse’s interest in the FLP; otherwise, income could not be distributed to either spouse. The combination of a SP agreement with a “preferred” FLP allows distributions of income to one spouse but not necessarily both spouses in the event of a CO.