HAMPTON ROADS
LITHOTRIPSY

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PETITION

Petition for New Technology and Equipment Policy

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

Hampton Roads Lithotripsy, LLC ("HRL") respectfully petitions the State Health Coordinating Council (SHCC) to add a new policy to the *2017 State Medical Facilities Plan (2017 SMFP)*. Specifically, HRL requests that the following language be added to form Policy TE-3:

> **Policy TE-3: Use of Existing Mobile Lithotripsy Units to Increase Access in Rural Areas of the State**
>
> Applicants that own existing mobile lithotripsy units that are approved to operate in states contiguous to North Carolina may apply for a Certificate of Need (CON) to serve host sites in North Carolina if the applicant(s) demonstrates in the CON application that the mobile lithotripsy unit:
>
> 1. Has regulatory approval, if needed, to operate in a state contiguous to North Carolina, including Georgia, South Carolina, Tennessee or Virginia;
>
> 2. Currently provides services to at least one host site in one of the states that is contiguous to North Carolina and commits to continue doing so following completion of the project;

3. Will serve only hospital sites in areas defined as rural by the United States Department of Agriculture[1], which includes areas other than:

    a. A city or town that has a population greater than 50,000 inhabitants; and,
    b. The urbanized area contiguous and adjacent to such a city or town.

4. Is reasonably expected to improve the quality of, access to, or value of lithotripsy services in the area served by the host site.

The performance standards in 10A NCAC 14C .3203 would not be applicable.

REASON FOR THE REQUESTED ADJUSTMENT

Of the technology methodologies in the *SMFP*, most have changed multiple times since they were first developed, particularly higher volume modalities, such as MRI and PET. On the other end of the spectrum, extracorporeal shock wave lithotripsy ("ESWL" or "lithotripsy") is a much lower volume service, and few petitions have been submitted for the technology since its inception. However, HRL believes there are multiple issues with the current lithotripsy methodology. While not all of these issues may be addressed through the addition of the policy requested by this petition, HRL believes that the negative impact of these issues, particularly on the rural and geographically isolated areas of the state can be adequately mitigated without the need to completely revamp the current methodology. These issues, the evidence for their existence, and the impact on access to lithotripsy services are provided below.

1. **The current methodology may understate the need.**

    The current methodology uses a ratio of urolithiasis (urinary stone disease, also referred to as nephrolithiasis) to population from the 2001 *Clinical Manual of Urology* of 16 per 10,000 people, based on the "annual incidence" of the disease. That number is multiplied by 90 percent, to account for the 10 percent of those with the disease that would not be appropriate for lithotripsy.

    From an epidemiological perspective, one problem with basing the projected need on an incidence rate is that incidence rates include only newly diagnosed cases. While this may be appropriate for a condition that is treated and, hopefully cured, within a relatively short timeframe (such as cancer), such is not the case for urolithiasis, which is a chronic condition that is not cured, but may occur many times over a person's lifetime, including multiple times within the same year. Thus, new cases only capture a portion of the need.

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1 For additional information, see http://eligibility.sc.egov.usda.gov/eligibility/welcomeAction.do?pageAction=rbs.

A more relevant statistic is to examine the prevalence of the disease, which, according to the most recent *Clinical Manual of Urology* is 8.8 percent, or 888 per 10,000[2]. While not all of these cases would require treatment in a given year (and thus, the 90 percent adjustment in the methodology would likely have to be changed), the number of people living with the disease, any of whom can have a stone develop at any time, is clearly much higher than the new cases estimated by the methodology's incidence rate.

In addition, research demonstrates that the prevalence of kidney stones is increasing, driven by changing (negative) trends in diet and obesity. Studies have also shown, unfortunately, that medical and surgical treatments for obesity also increase the incidence of nephrolithiasis in patients that have undergone these treatments. The combination of population growth and continued increase in the prevalence of diabetes and obesity are projected to dramatically increase the incidence and cost of treating kidney stones[3]. Since ESWL is an effective way of treating the occurrence of stones on an outpatient basis without the cost of hospitalization or invasive surgery, HRL believes the methodology should ensure adequate access to lithotripsy services, particularly as the number of patients with the condition increases. HRL also notes that the incidence rate used in the current methodology is based on a 2001 publication, and is therefore likely based on data from the late 1990s or earlier. Given the growth in the prevalence of the disease, it is reasonable to believe that the incidence rate, much less the prevalence rate, is much higher today.

2. **The actual number of lithotripsy procedures is lower than what is projected, even using the current methodology, which indicates a potential access issue.**

Unlike most of the other technology modalities (e.g. MRI, PET, cardiac catheterization), which project need based on the historical utilization of existing equipment, the *SMFP* methodology for lithotripsy attempts to estimate need based on the incidence rate for the disease, as discussed in the previous point. One of the limitations of this methodology is that it masks actual utilization that is lower than expected, but continues to generate need based on the ratio of projected procedures to population. Since the methodology is also statewide, it fails to account for areas in which there may be an imbalance of equipment, leading to access issues and lower than expected utilization.

These issues are clear when the ratio in the methodology is compared with the actual total number of procedures performed statewide. As reported in the *2016 SMFP*, much fewer procedures are being performed than expected; specifically, 10,459 procedures were reported for FFY 2014. For a statewide population of

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2 This book is a copyrighted document, not available in the public domain; therefore, HRL cannot provide a copy with this petition.

3 Some of these studies are copyrighted; please see Attachment 1 for a copy of the articles that are publically available and the abstracts for those that are not.

9,953,687 in 2014, that equates to a rate of 10.5 per 10,000, much lower than the incidence rate of 16 per 10,000 used in the methodology. As shown in the table below, the number of procedures performed in the last five years has fluctuated from year to year, with only a small growth rate trend over the five year period.

SMFP Year	*Lithotripsy Procedures Reported*
2012	10,171
2013	10,456
2014	10,562
2015	10,194
2016	10,459
CAGR*	0.7%

Source: 2012-2016 SMFPs
*CAGR = Compound Annual Growth Rate

To determine need for additional lithotripters, the current methodology applies the incidence rate to the projected population. For example, in the *2016 SMFP*, the methodology applies the incidence rate of 16 per 10,000, to the 2016 population of 10,157,928, (reduced by 10 percent per Step 2 of the methodology), generating an expected number of 14,627 procedures. While that number has generated the need for another mobile lithotripsy unit in the state based on the assumed capacity of lithotripsy units, HRL does not believe that the addition of one more lithotripsy unit is likely to help expand access to all areas of the state. Moreover, HRL does not believe that it is likely that the addition of one more unit of equipment is likely to increase the number of procedures done in the state by 40 percent, as implied by the assumptions in the methodology. (14,627 projected procedures for 2016 – 10,459 actual procedures in 2014 = 4,168 procedures, or 40 percent more than were performed in 2014).

Thus, notwithstanding the potential understated need as described in #1 above, the number of procedures projected by the methodology is significantly higher than the number actually being performed in the state. HRL believes that this indicates a potential access issue, in that some areas of the state are underserved. Unfortunately, the Registration and Inventory of Medical Equipment forms for lithotripters does not request data for patient origin, so a more specific determination of the actual use rate by county is not available.

3. **The methodology assumes capacity that is unavailable to most areas of the state.**

The methodology uses a statewide methodology and counts the total number of lithotripsy units providing service anywhere in the state. Included among these is one fixed unit, which is located in Asheville, in the western part of the state.

Clearly it is not reasonable to expect residents in most of the state to use this unit. Of the 13 remaining mobile units, five of them serve sites in both North Carolina and another state (either SC or VA). Collectively, these out-of-state sites accounted for 1,036 procedures in FFY 2014, or the capacity of one full mobile unit. Given the difference between expected and actual utilization across the state, HRL believes that the unavailability of both the fixed unit in Asheville as well as the mobile capacity serving other states may limit access to the service.

4. **The need for additional access to the service appears particularly great in more isolated, rural areas of the state.**

Table 9A in the *2016 SMFP* shows the sites served by the existing mobile lithotripsy units in the state and the number of procedures performed. An examination of these tables shows that the units serving the more highly and densely populated areas of the state, particularly the three major metro regions (Charlotte, the Triad and the Triangle), as well as sites within a reasonable travel time of those areas, are more effectively utilized. The units serving the rural parts of the state, particularly far Western and Northeastern North Carolina are not as well utilized. Based on its experience providing mobile lithotripsy service, HRL believes that this is likely because of the difficulties serving such a large geographic region with mobile technology. Further, given the nature of lithotripsy services, if the mobile units are not readily available to treat patients within a short timeframe, patients may opt for other treatment methods or be forced to travel out of state to be treated.

HRL has treated some of these patients who reside in northeastern North Carolina but have minimal access to lithotripsy in their state. These patients are often referred to sites in Virginia which are some distance away from the patients' homes and families. This area of the state is one of the most isolated and distant from the metropolitan areas of North Carolina. It is also underserved by lithotripsy service. While multiple mobile units serve other parts of the state, only one unit serves northeastern North Carolina (with sites in Chowan, Dare and Pasquotank counties). According to information from the 2015 Registration and Inventory of Medical Equipment forms[4] for that provider, it was in the state only 47 days in 2014, less than two full months. During 2014, a total of 92 procedures were performed. The total population of the region (including Camden, Chowan, Currituck, Dare, Gates, Hertford, Pasquotank, Perquimans, Tyrell, and Washington counties), which are served by the hospitals representing the three mobile sites, is 191,291. Even using the understated 16 per 10,000 incidence rate from the current methodology, the population should generate at least 306 new urolithiasis cases per year, and if 90 percent received lithotripsy, that would equate to 275 procedures. If the historical use rate of 10.5 procedures per 10,000 is used (as discussed in #2 above), the area should still generate more than 200 procedures per year.

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4 Forms for 2016 were not available at the time of the filing of this petition.

Although the provider does not report by county of patient origin, it is clear that patients from this part of North Carolina are either 1) forgoing treatment and enduring prolonged, extreme and unnecessary pain; or, 2) are being forced to seek care at some distance from their home county, which requires unnecessary travel and expense. According to 2015 records from Hampton Roads Lithotripsy's urologists, approximately 10 percent of their patients live in North Carolina but were treated at sites in Virginia. These patients could have been treated in North Carolina if the providers and services were available closer to home and with sufficient service to provide care in a timely manner.

HRL believes it is also important to consider that hospitals in more rural areas also lack a choice among providers, which may drive up the cost of providing the service. Given the lack of mobile units serving the most remote and rural parts of the state, it is likely that hospitals wishing to provide lithotripsy services have only one option—and thereby limited ability to negotiate rates with the mobile vendor. The results of this issue for other services have been well-recognized by the SHCC, specifically with the recent addition of Policy TE-1 and the special need adjustment for a fixed MRI to serve a hospital in Brunswick County in the *2016 SMFP*. In both of these instances, the SHCC recognized that while some hospitals may already be served with a vendor-provided service, access may still be limited due to the lack of competition for that service. The proposed new policy will similarly provide more competition in underserved areas of the state, without necessitating the addition of the full capacity of one or more lithotripters in the state.

5. **Other health factors show that the incidence and prevalence of urolithiasis is likely higher in northeastern North Carolina than the rest of the state.**

Of even greater concern, given the health factors associated with urolithiasis, HRL believes that there are likely an even higher percentage of patients with the disease in northeastern North Carolina (as a prime example of a rural, isolated part of the state) than much of the rest of the state. According to the *Clinical Manual of Urology* as well as the articles included or referenced in Attachment 1, obesity and diabetes are health conditions associated with higher rates of kidney stones. As shown in the table below, of the counties listed above, all but one (Dare) have obesity rates well above the state average.

County	***Obesity Rate***
Camden	31%
Chowan	32%
Currituck	31%
Dare	28%
Gates	34%

Hertford	33%
Pasquotank	35%
Perquimans	34%
Tyrell	31%
Washington	34%
NC Average	**29%**

Source: County Health Rankings for 2015, published by the RWJ Foundation, accessed at www.countyhealthrankings.org.

Not surprisingly, the percentage of adults with diabetes is also higher in most counties (all but Dare) than the statewide average of 11 percent, as shown in the table below.

County	***Diabetes Rate***
Camden	11%
Chowan	14%
Currituck	11%
Dare	9%
Gates	11%
Hertford	14%
Pasquotank	14%
Perquimans	15%
Tyrell	13%
Washington	15%
NC Average	**11%**

Source: County Health Rankings for 2015, published by the RWJ Foundation, accessed at www.countyhealthrankings.org.

These trends are similar elsewhere in the state, where the rates of obesity and diabetes are higher in rural areas, and generally at or below the state average in more urban areas. Given the major role these factors play in the formation of kidney stones, HRL believes that the need for expanded lithotripsy capacity in the rural and isolated areas of the state, including northeastern North Carolina, is significant.

6. **The standard need methodology is unlikely to address these issues effectively.**

HRL is aware that the standard need methodology has resulted in the allocation of an additional mobile lithotripter in the state in the *2016 SMFP*. HRL considered applying for this need; however, it does not believe that the addition of another mobile lithotripter in the state will have a significant impact on increasing access in the more rural areas of the state, such as northeastern North Carolina.

The primary barrier to an applicant being successful in proposing to serve rural areas of the state with a new lithotripter is the performance standards in the CON rules. Specifically, 10A NCAC 14C .3203(2) requires applicants to demonstrate that the new equipment will perform 1,000 procedures per year in the third year of operation. While that may be a reasonable target to ensure effective utilization of new equipment, it is a challenge for new providers, particularly those who wish to serve rural areas of the state. Although the need for access and more capacity may be greater in the rural areas, the lower population of those areas does not generate as many procedures, thereby requiring equipment to serve many more sites than equipment serving more populous areas. This creates not only logistical issues in traveling to more sites, but also makes obtaining a CON more difficult, particularly in a competitive review, since the applicant must identify and secure some level of commitment from the host sites it intends to serve. Moreover, based on the historical application of similar CON rules, an applicant proposing a new lithotripter would need to demonstrate the need (i.e. the 1,000 procedures) based on sites in North Carolina only. Thus, the ability to serve sites in multiple states in order to more effectively achieve the minimum volume requirements would not be possible.

The 1,000 procedure threshold is also difficult to achieve, given the actual historical average number of procedures provided by the existing equipment in the state. As shown in the *2016 SMFP*, the existing equipment currently provides an average of only 747 procedures per unit, less than 75 percent of the CON rule requirement for what new applicants must project to achieve by the third year of operation. As noted above, the units that currently meet or exceed this threshold serve primarily the urban areas of the state and areas within a reasonable distance for the mobile equipment to travel overnight. Thus, HRL believes that applying under the standard allocation is not likely to be successful.

Rationale for Specific Components of Proposed Policy

While all of these issues may seem to indicate the need for revisions to the lithotripsy methodology, and though HRL does agree that the current methodology does not appear to meet the need in some of the rural and outlying areas of the state, HRL believes that a more simple approach is the addition of the proposed policy. Rather than adding a completely new unit of lithotripsy equipment to the inventory, which, as noted above, would likely be required to provide at least 1,000 procedures within North Carolina, HRL believes it is a more effective policy to allow existing equipment from other states to serve the underserved areas of the state. This would expand access to those areas without requiring the expense and capacity of new unit being added to the inventory. To ensure that the equipment proposed to be used under this policy is not additional equipment, HRL has proposed conditions 1 and 2, which require an applicant to demonstrate that the equipment already exists and is serving site in contiguous states, and will continue to do so in the future. HRL believes these conditions will also prevent providers from other states from "picking up and moving" their equipment into North Carolina, but will require them to continue serving the state(s) they currently serve.

HRL also believes that this policy should remain limited to lithotripsy services, at least in its present form. While multiple modalities serve residents with mobile equipment, including MRI and PET, HRL does not believe the same issues exist for these modalities. In particular, the other modalities generate much higher volume than lithotripsy, meaning that the mobile providers can effectively and efficiently serve fewer sites, including rural areas. Unlike lithotripsy, both MRI and PET are also provided by a significant number of fixed sites throughout the state.

The definition of "rural" proposed in the policy is one that HRL believes strikes an appropriate balance and more accurately identifies the areas of the state that would likely need additional access to the service. Specifically, some definitions of "rural" exclude any area that is part of an MSA, while others may include counties below certain population thresholds, but which are clearly part of the suburban area around a major metropolitan area. The definition used by the USDA and proposed in this petition is clear and able to be verified by inputting the address of the facility into the website referenced above. HRL considered proposing a population number as limitation, such as counties with fewer than 100,000 population; however, quite a number of counties with populations under 100,000 are located close enough to urban counties to be served by existing lithotripters. HRL also considered using the definition originally used in the *Proposed 2015 SMFP* for Policy TE-1 (Conversion of Fixed PET Scanners to Mobile PET Scanners); however, given the discussion concerning that definition and its deletion from the final *2015 SMFP*, HRL determined that the proposed USDA definition may be more appropriate. HRL would not be opposed to a different definition of rural, if the SHCC believes another would be more suitable; however, it should be noted that not all rural counties, particularly those without hospitals, would be appropriate for mobile lithotripsy service.

HRL also believes that an important component of the proposed policy is the requirement that applicants demonstrate how they would positively impact the basic policies of the *SMFP*. To that end, HRL does not intend that the proposed policy would be used by applicants to simply "replace" existing capacity, but it does believe that applicants should be able to serve sites that are currently being served by other entities, if they can demonstrate that they will improve quality, access or value. For example, an applicant may be able to demonstrate that it will increase the number of days of service to the site, or lower the cost of the service to the host site, or improve the quality of the service provided compared to the existing provider. HRL believes that the residents of North Carolina would be well served by allowing an existing lithotripter into the state on a limited basis under these conditions.

Finally, the policy would allow applicants to forgo the required utilization standards in the CON rules. Since the policy would require applicants to use existing equipment that is already serving sites in other states, and since the equipment would be limited to serving sites in rural areas with lower volume than urban sites, applicants should not be required to project achieving the same volume standards as applicants serving only North Carolina with a new unit. To require applicants to achieve the same volume standards would effectively negate the ability of providers to offer service to rural areas under the policy.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

HRL believes the issues described above, particularly the lack of access in rural and geographically isolated parts of the state, are unlikely to be addressed without the approval of the proposed new policy. Patients in rural areas will continue to delay treatment while enduring intense pain, or will have to leave the state to access care elsewhere.

ALTERNATIVES CONSIDERED

File a Petition for a Special Need Adjustment

HRL considered waiting until the summer petition cycle to file a petition for an adjusted need determination. However, since the current lithotripsy methodology is statewide, it is likely that another need determination would also be for the state as a whole, not the rural and isolated areas of the state that HRL is attempting to impact through the proposed policy addition. Moreover, an adjusted need determination would likely still require an applicant to acquire a new lithotripter to provide at least 1,000 procedures in North Carolina. HRL believes a more reasonable and cost-effective approach is to allow providers that operate in contiguous states to bring existing equipment into North Carolina, as needed to expand access to the service in rural areas. It should be noted, however, that if the SHCC believes a special need adjustment would be a more prudent approach, HRL would consider filing such a petition in the summer.

Recommend Changes to or Deletion of the Lithotripsy Methodology

HRL also considered recommending that the current methodology be changed to address some of the issues noted above, or taken out completely. While the acquisition of a lithotripter is "per se" reviewable per the CON statute, meaning that it requires a CON regardless of cost, the statute does not require a need methodology in the *SMFP*. Providers could simply apply for a CON for the equipment and demonstrate need in the CON application, similar to the process for GI endoscopy rooms or heart-lung bypass machines today. Most of the other states that require a CON for lithotripsy do not have a methodology to allocate need as the *SMFP* does, but require applicants to demonstrate the need within the application.

Alternatively, the methodology could be changed in ways to address the access issues shown above, such as: excluding the capacity of fixed lithotripters or procedures provided in other states; determining need by service area such as HSA or other multicounty group; or, changing from an incidence rate to a utilization-driven methodology. While any of these alternatives may be reasonable, HRL is aware of the challenges with developing new methodologies, particularly the time needed to develop a workgroup, examine new approaches and present those findings to the SHCC. In addition, the methodology has not received many petitions in recent years, so it is likely effective for much of the state. Thus, HRL believes that the proposed policy will provide the access needed with minimal impact in the majority of the state, where the methodology may be working as intended.

THE PROPOSED CHANGE WOULD NOT LEAD TO UNNECESSARY DUPLICATION

HRL believes the proposed policy clearly avoids unnecessary duplication. Rather than allocating the capacity of an entire additional lithotripter to the state, Policy TE-3 would allow the introduction of only the additional capacity that is needed to serve rural and isolated areas of the state. Further, applicants would need to demonstrate that their proposals would be consistent with the basic principles of the *SMFP*, as described in detail below. Finally, unlike a special need determination, given the conditions of the proposed policy, applicants would have to demonstrate that their proposal was necessary duplication, as defined by improving access, quality or value of the service.

HRL recognizes that the SHCC would need to consider how to treat the additional capacity added by the lithotripters that are allowed to serve sites in the state under the proposed policy. Although several of the existing units in the state do serve out-of-state sites, as noted above, and though the capacity of those units is not discounted to account for the procedures provided in other states, HRL does believe that it would be prudent to account for the additional capacity provided through the proposed policy. Based on the assumed capacity of 1,000 procedures per year, if the equipment is available 250 days per year, the capacity is 4.0 procedures per day. This capacity is also consistent with the capacity definitions used in the CON rules for mobile lithotripters. The SHCC could assign a capacity of 4.0 procedures for every day that a mobile lithotripter approved under this policy is on site at a North Carolina hospital. By doing so, the SHCC could ensure that the additional volume generated by these units did not inadvertently lead to the allocation of additional unnecessary lithotripters under the standard methodology.

THE PROPOSED CHANGE IS CONSISTENT WITH THE BASIC PRINCIPLES

Consistency with the basic principles is a requirement of the proposed policy. However, more than merely demonstrating that an application is consistent with these policies, as all CON applicants must currently do, under the proposed policy, an applicant would be required to demonstrate that its proposal would improve lithotripsy service with respect to the basic principles, either by expanding access, improving quality or by increasing the value of the service provided.

CONCLUSION

HRL believes that the proposed addition of Policy TE-3 to the *2017 SMFP* is the most effective way to address the current maldistribution of lithotripsy services in the state. These issues, combined with the CON requirements of an applicant seeking to add the capacity of an additional lithotripter in the state, will continue to make it difficult for new or existing providers to effectively serve the rural and geographically isolated areas of the state. The proposed policy will enable providers to serve those areas—and only those areas—without unnecessarily duplicating the existing equipment that provides adequate service to more urban populations, while increasing access, quality and value of lithotripsy services to the residents of North Carolina.

Attachment 1

Use of the National Health and Nutrition Examination Survey to Calculate the Impact of Obesity and Diabetes on Cost and Prevalence of Urolithiasis in 2030

The publisher's final edited version of this article is available at Eur Urol
See other articles in PMC that cite the published article.

Abstract

Background

The prevalence of urolithiasis and its risk factors such as obesity and diabetes have increased over time.

Objective

Determine the future cost and prevalence of kidney stones using current and projected estimates for stones, obesity, diabetes, gender, and population rates.

Design, Setting, and participants

The Stone prevalence in 2000 was estimated from National Health and Nutrition Examination Survey (NHANES) 1988–1994 and 2007–2010. The cost per percent prevalence of stone disease in 2000, calculated using Urologic Diseases in America Project data, was used to estimate the annual cost of stones in 2030, adjusting for inflation and increases in population, stone prevalence, obesity, and diabetes rates.

Outcome measurements and statistical analysis

The primary outcome was prevalence and cost of stones in 2030. The secondary outcomes were the impact of obesity and diabetes on these values, calculated using ratios for stones by body mass index and diabetes status.

Results and limitations

The annual cost of stone disease in 2000, adjusted for inflation to 2014 US dollars, was approximately $2.81 billion. After accounting for increased in population and stone prevalence from 2000, the estimated cost of stones in 2007 in 2014 US dollars was $3.79 billion. Future population growth alone would increase the cost of stone disease by $780 million in 2030. Based on projected estimates for 2030, obesity will independently increase stone prevalence by 0.36%, with an annual cost increase of $157 million. Diabetes will independently increase stone prevalence by 0.72, associated with a cost increase of $308 million annually by 2030. NHANES data, however, capture patient self-assessment rather than medical diagnosis, which is a potential bias.

Conclusions

The rising prevalence of obesity and diabetes, together with population growth, is projected to contribute to dramatic increases in the cost of urolithiasis, with an additional $1.24 billion/yr estimated by 2030.

Patient Summary

Obesity, diabetes, and population rates will contribute to an estimated $1.24 billion/yr increases in the cost of kidney stones by 2030.

Keywords: urolithiasis, cost, obesity, diabetes

1. Introduction

An assessment of the National Health and Nutrition Examination Survey (NHANES) II and III datasets revealed that the prevalence of kidney stones in US adults rose significantly, from 3.2% in 1976–1980 to 5.2% in 1988–1994[1]. This trend has persisted with the latest NHANES data revealing an estimated 8.8% prevalence of stone disease[2].

The concomitant rise in comorbid conditions associated with stone disease, including obesity and type 2 diabetes mellitus, has been proposed as a possible explanation for the rise in stone prevalence. In US adults, the prevalence of obesity increased from 30.5% in 2000 to 35.7% in 2010[3], and the age-adjusted prevalence of diabetes rose from 4.5% in 1995 to 8.2% in 2010[4]. Both conditions have been linked to an increased risk of uric acid and calcium oxalate stone formation by a variety of proposed pathophysiologic mechanisms[5–11].

Several studies have verified the positive association between body size and risk of stone formation[2,12–15]. In addition, obese first-time stone formers have been shown to have an increased incidence of stone recurrence and a decreased time to recurrence compared to nonobese first-time stone formers[16].

The associations between obesity, diabetes and nephrolithiasis have been well established and the pathophysiologic mechanisms are currently being studied, but the impact of these comorbid conditions on cost and prevalence of stone disease has yet to be explored. In 2000 the total annual expenditure for urolithiasis was estimated at $2.1 billion, representing a 50% increase from estimates in 1994[17]. The effect of obesity and diabetes on nephrolithiasis is likely to escalate the financial burden of this increasingly common condition. The aim of the present study was to calculate the effects of population, obesity, and diabetes on future costs of nephrolithiasis, specifically in the year 2030, using current and projected prevalence estimates of obesity, diabetes, population, and stone disease.

2. Methods

This study was exempt from review by our institutional review board because it does not include patient data.

2.1 Prevalence of stone disease in 2000

Because cost estimates for urolithiasis in the US have been reported for the year 2000, cost and estimated prevalence of stone disease from that year were used to derive the cost per unit percentage prevalence that could then be applied to a year for which we had prevalence but no cost data. Since no available national prevalence data spanned the year 2000, the prevalence of stones for that year was estimated by calculating the mean stone prevalence for the 1988–1994[1] and the 2007–2010[2] NHANES datasets. NHANES is a nationally representative, multistage probability survey assessing the health and nutritional status of the noninstitutionalized US population. Since there are more women than men in the United States, the stone prevalence was corrected for gender distribution (Table 1)[18].

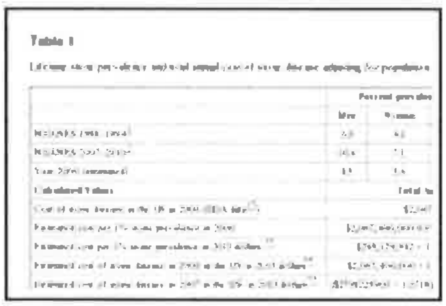

Table 1

2.2 Cost per percent prevalence of stone disease in 2014 US dollars

The estimated cost for the diagnosis and management of nephrolithiasis for the year 2000 was obtained using data from the Urologic Diseases in America Project[17]. This cost was divided by the estimated lifetime prevalence for stone disease in 2000 to determine the cost per unit percentage prevalence of stones for that year. Year 2000 costs were then converted to 2014 dollars using an inflation calculator based on the US government Consumer Products Index to provide contemporaneous values (Table 1).

2.3 Population Estimates

Using the US Census Bureau's Population Estimates Program, which estimates yearly population in the United States from current data on births, deaths and migration to update the most recent decennial census, the total US population, as well as the percentage of men and women, was determined for 2007[18], a year for which the most current stone prevalence has been published[2]. An estimate of cost increase based on the increase in population was then determined using prevalence of stone disease from 2007–2010 NHANES data[2], adjusting for gender distribution[18] (Table 1). Population projections for 2030 were obtained from the US Census Bureau[19].

2.4 Impact of obesity on cost

The standard categories of body mass index (BMI) in kilograms per square meter, as defined by the Centers for Disease Control and Prevention (CDC), are normal (18.5–24.9 kg/m^2), overweight (25.0–29.9 kg/m^2), and obese (≥30.0 kg/m^2)[20]. The distribution of normal, overweight, and obese individuals in 2007 was obtained from NHANES data. These distributions were applied to the prevalence of stone disease from 2007–2010 NHANES data and the odds ratios for stone prevalence by weight category (1=normal BMI, 1.29=overweight, and 1.55=obese)[2] to calculate the percentage prevalence of stone disease based on anticipated 10% shift from normal to overweight BMI and overweight to obese BMI in the US population. This method was chosen because the CDC projects that >44% of US adults (approximately a 10% increases from current prevalence) will be obese by 2030[21]. The CDC's analysis is based on a model that projects that around 50% (95% confidence internal [CI], 45–55) of US adults will be obese by 2030(Table 2).

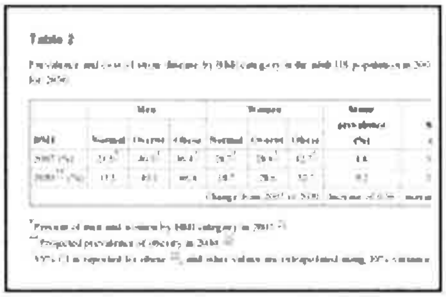
Table 2

2.5 Diabetes Prevalence

The percentage of diagnosed and undiagnosed diabetes rates among individuals ≥20 yr in the United States in 2007 was obtained from the CDC's National Diabetes Mellitus Fact Sheets[22]. These estimates were derived from the 2003–2006 NHANES, the 2004–2006 National Health Survey, 2005 Indian Health Service data, and 2007 resident population estimates. The odds ratio for a history of stone disease associated with a diagnosis of diabetes, independent of BMI and gender was previously reported as 1.59[2]. This value was used to calculate the percentage prevalence of stone disease in 2030 applying extrapolated estimates from previously published projections of diabetes prevalence by gender for 2030 (Table 3)[23].

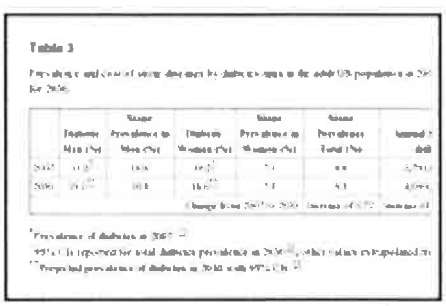
Table 3

3. Results

The average lifetime prevalence of stone disease in 2000 was calculated as 7.0% (8.5% in men and 5.6% in women). Assuming an annual expenditure for stone disease in 2000 of approximately $2.1

billion[17], the cost per percentage prevalence of stone disease in 2000 was approximately $295 million. After adjusting for 35.8% inflation from 2000 to 2014, the cost per percent prevalence of stone disease in 2014 US dollars was $401 million, and the total cost of stone disease in 2000 in 2014 US dollars was approximately $2.81 billion (Table 1).

The US population in 2000 was 281,421,906[24]. In 2007, the population grew to 301,621,157 and was composed of 50.7% women and 49.3% men[18]. The calculated cost of stone disease, accounting for the 1.07–fold increase in the population from 2000 to 2007 and a 1.26-fold increase in stone prevalence from the calculated estimate in 2000 to the NHANES estimate for 2007–2010[2], resulted in an annual cost of $3.79 billion for stone disease in 2007, a year included in the most current available stone prevalence for US adults. The US Census Bureau estimate for the 2030 US population is 363,584,435, representing a 1.29 increase from 2000, which would be associated with an annual cost of stone disease of $4.57 billion in the unlikely event that stone prevalence remained constant from 2007 to 2030. Therefore, population growth alone is expected to increase the annual cost of stone disease by $776 million from current estimates by the year 2030 (Figure 1).

Cost of stone disease in 2007 and the future based on obesity, diabetes, and population growth

After adjusting for gender distribution, the prevalence of stone disease in 2007 was 8.8%[2]. As shown in Table 2, we project a total lifetime prevalence of stone disease of 9.2% (95% CI, 8.3–10.1) if there is a 10% shift in normal weight to overweight and overweight to obese in men and women in the United States, as expected by 2030[25].

This change in obesity prevalence alone would result in a 0.36% absolute increase in stone prevalence by 2030. As such, for every 10% increase in obesity, the annual cost of stone disease is expected to be $3.95 billion (95% CI, 3.55 billion to 4.34 billion) representing a $157 million increase from 2007 to 2030 (Figure 1).

Table 3 shows that in 2007, the total reported prevalence of diagnosed and undiagnosed diabetes in adults ≥20 yr was estimated at 11.2% for US men and 10.2% for US women[22]. A 1.59-fold higher prevalence of urolithiasis has been reported among individuals with diabetes compared to nondiabetic individuals[2]. Using this odds ratio, we estimate that if the prevalence of diabetes increases as projected[23], this factor alone will independently increase stone prevalence to 9.5% (95% CI, 3.62–4.58), representing an increase of $308 million by 2030(Figure 1).

Taking into account the projected increase in population, diabetes and obesity, the increase in the total cost of stone disease from 2007 to 2030 will be $1.24 billion in 2014 US dollars, without taking into account other factors that influence stone prevalence.

4. Discussion

This analysis represents the first published attempt to quantify the effects of population growth and rising rates obesity, and diabetes on the prevalence and cost of stone disease. In addition, projected future costs that might be incurred as a result of population growth and increasing prevalence of these comorbid conditions are described in this paper. We chose to project estimates for 2030, a year in the near future for which high-quality estimates of obesity and diabetes exist. We showed that population growth alone will have the most profound impact on increasing the annual cost of stone disease. The cost of stone disease in 2000 was approximately $2.1 billion annually[17]. After accounting for increases in population and stone prevalence from 2000, the estimated cost of stone disease in 2007 in 2014 US dollars was $3.79 billion. We calculated that in the unlikely event that stone prevalence remains unchanged from the last national published estimate[2], the population growth expected by 2030 will independently increase the annual cost of stone disease by a staggering $ 780 million. Population growth is largely a nonmodifiable factor, but we showed that potentially modifiable factors such as obesity and diabetes are related to escalations in stone disease prevalence that contribute, though not as significantly as does population growth, to substantial increase in the cost associated with urolithiasis.

The data for much of our investigation are derived from the 2007 NHANES by Scales et al[2], which represents the most recent assessment of kidney stone prevalence since Stamatelou and colleagues analyzed 1976–1994 NHANES data[11]. Because of established associations among obesity, diabetes, and stone disease, Scales and colleagues created multivariable models to quantify the independent relationship of these factors to stone disease and subsequently generated odds rations, which we used in our analysis.

The CDC released rates of current and future obesity in August 2012[25]. Twelve states have an adult obesity rate exceeding >30%. If obesity continues at the current rate, the CDC projects that >44% of US adults (a 10% increase from current rates) will be obese by 2030. A 10% increase from normal to overweight and overweight to obese would independently account for an additional $157 million in annual cost of stone disease, based on our calculations.

We acknowledge that obesity and diabetes are interrelated entities, and therefore an increase in one will produce a concomitant increase in the other. However, the two conditions were independently associated with a greater prevalence of urolithiasis in the latest NHANES data set[2]. Therefore, the independent impact of diabetes on stone prevalence will likely still be realized, as a dramatic rise in the prevalence of diabetes – to nearly 1 in 10 US adults – is anticipated by 2030. We estimate that the independent effect of this projected rise in diabetes will increase the cost of stone disease by $73million by 2030.

Using projected estimates of population, obesity, and diabetes, we predict that the annual cost of stone disease will increase by 33% in the year 2030 totaling an additional $1.24 billion/yr annually, without taking into account other factors that influence stone prevalence. In any case, these figures are likely underestimated, since the cost of health care has outpaced inflation[26].

The epidemiological literature supports the metabolic associations that have been demonstrated among obesity, diabetes, and stone formation. Curhan and coworkers showed that the prevalence and incidence of stone disease were positively associated with body weight and BMI[12]. Weight gain, a process that likely involves the addition of proportionally more adipose tissue compared with lean muscle, was associated with an increased rate of incident stone formation[15]. Semins and associates also examined the relationship between BMI and stones using claims data and found an increasing risk of kidney stones with increasing BMI up to a BMI of 30 kg/m^2, after which the risk stabilized[14].

Our estimates of the effects of obesity and diabetes on the prevalence and cost of stone disease would be incomplete without including the impact of population growth. When attempting to consolidate the individual contribution of obesity, diabetes, and population change on stone disease, the magnitude of each has to be weighted. Although the published odds ratios for diabetes and obesity provided this information for the analysis of current prevalence and cost estimates[2], any projected future estimates must take into account the rate of change of each factor. In addition, the incidence of stones peaks in the fourth to sixth decade of life[27]. As such, the direct and indirect costs of stone disease in this working age group are substantial[28]. While an age-stratified analysis could provide insight into cost contributions of certain subgroups of the population, this level of data granularity for specific age groups was lacking and precluded this type of analysis. The majority of population gains in the future will be in older segments of the population.

Although this analysis represents the first estimate of the impact of population growth, obesity and diabetes on current and future costs of stone disease, our results must be tempered by some inherent limitations. First the NHANES instrument from which we derived much of our data is a cross-sectional design that uses patient self-assessment of stone disease and not confirmed medical diagnoses. Scales et al also recognized this limitation in their analysis and additionally considered a secondary outcome of self-reported stone passage that reflected symptomatic stones and found similar results regarding stone prevalence[2]. Any prevalence data are limited by the inability to diagnose asymptomatic stones. In addition to NHANES, we used data derived from several other large databases, which leads to inherent bias. Finally, our analysis failed to take into account other important demographic factors, such as race/ethnicity, geography, and socioeconomic status, that may change unpredictably over time and effect stone prevalence independently, as well as rates of diabetes and obesity. The incorporation of these variables into future analyses will provide a more fine-tuned estimate of current and future costs.

5. Conclusions

In this paper we present a sound analysis of the most current data regarding stone prevalence, obesity, diabetes, and population changes and their effects on cost both today and in the future. Obesity and diabetes are somewhat modifiable diseases that affect stone prevalence, and as demonstrated in this paper, their rising incidence, in conjunction with population growth, will lead to substantial increases in future stone-related health care costs.

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Prevalence of Kidney Stones in the United States

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Abstract

Background—The last nationally representative assessment of kidney stone prevalence in the United States occurred in 1994. After a 13-yr hiatus, the National Health and Nutrition Examination Survey (NHANES) reinitiated data collection regarding kidney stone history.

Objective—Describe the current prevalence of stone disease in the United States, and identify factors associated with a history of kidney stones.

Design, setting, and participants—A cross-sectional analysis of responses to the 2007–2010 NHANES (n = 12 110).

Outcome measurements and statistical analysis—Self-reported history of kidney stones. Percent prevalence was calculated and multivariable models were used to identify factors associated with a history of kidney stones.

Results and limitations—The prevalence of kidney stones was 8.8% (95% confidence interval [CI], 8.1–9.5). Among men, the prevalence of stones was 10.6% (95% CI, 9.4–11.9), compared

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Study concept and design: Scales, Saigal.
Acquisition of data: Smith, Hanley, Saigal.
Analysis and interpretation of data: Scales, Smith, Hanley, Saigal.
Drafting of the manuscript: Scales.
Critical revision of the manuscript for important intellectual content: Smith, Hanley, Saigal.
Statistical analysis: Scales, Smith, Hanley.
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with 7.1% (95% CI, 6.4–7.8) among women. Kidney stones were more common among obese than normal-weight individuals (11.2% [95% CI, 10.0–12.3] compared with 6.1% [95% CI, 4.8–7.4], respectively; $p < 0.001$). Black, non-Hispanic and Hispanic individuals were less likely to report a history of stone disease than were white, non-Hispanic individuals (black, non-Hispanic: odds ratio [OR]: 0.37 [95% CI, 0.28–0.49], $p < 0.001$; Hispanic: OR: 0.60 [95% CI, 0.49–0.73], $p < 0.001$). Obesity and diabetes were strongly associated with a history of kidney stones in multivariable models. The cross-sectional survey design limits causal inference regarding potential risk factors for kidney stones.

Conclusions—Kidney stones affect approximately 1 in 11 people in the United States. These data represent a marked increase in stone disease compared with the NHANES III cohort, particularly in black, non-Hispanic and Hispanic individuals. Diet and lifestyle factors likely play an important role in the changing epidemiology of kidney stones.

Keywords

Urinary lithiasis; Epidemiology; National Health and Nutrition Examination Survey

1. Introduction

Urinary stone disease is common and poses a significant health care burden in a working-age population. In 1994, data from the National Health and Nutrition Examination Survey (NHANES) estimated the prevalence of stone disease at 6.3% among men and 4.1% among women [1]. More recent analyses of claims data suggest rising utilization of health care resources for treating patients with stone disease [2,3]. However, there has been no nationally representative assessment of the prevalence of kidney stones in the United States since 1994. Thus, it remains unclear whether the claims data reflect changing patterns of care or changes in the epidemiology of kidney stones.

Recent investigations suggest that dietary and lifestyle factors play an important role in the risk of stone disease. Prospective data from the Health Professionals Follow-up Study and the Nurses' Health Study I and II note associations between incident stone disease and weight gain, body mass index (BMI), and diabetes mellitus [4,5]. These findings, combined with an obesity epidemic [6], support the hypothesis that the epidemiology of stone disease in the United States is changing.

Given this context, we sought to describe the current epidemiology of stone disease using a population-based cohort. We used data from the 2007–2010 NHANES sample to estimate the prevalence of stone disease in the United States. In the context of dramatically increasing obesity, we hypothesized that the prevalence of stone disease would be higher than 13 yr previously, when these data were last queried by NHANES III.

2. Methods

2.1. Data source

We used data from the 2007–2010 NHANES. NHANES is a stratified, multistage probability survey of the noninstitutionalized US population. The institutional review board of RAND Corporation determined that the study design was exempted from the requirement for review.

2.2. Study population

The study population consisted of all participants responding to the questions regarding a history of kidney stones contained in the household survey component. These data were used to determine the population prevalence of stone disease. The participants in the medical examination component were used to identify risk factors associated with a history of kidney stones.

2.3. Outcomes

The primary outcome for the analysis was the response to the question, "Have you ever had kidney stones?" Since some stones may be incidental findings on abdominal imaging, our secondary outcome was based on participant response to the question, "How many times have you passed a kidney stone?" We considered any subject who reported passing at least one stone as having a history of symptomatic stone disease.

2.4. Covariates

Subject age and gender were used as reported in the public-use NHANES data. We used the racial and ethnic group variable reported by NHANES based on survey responses to questions about racial group and ethnicity. We combined responses from the NHANES categories of Mexican-American and Other Hispanic into a single Hispanic category according to analytic guidelines [7]. Otherwise, we used the racial/ethnic groups as reported by NHANES. We included household income as a measure of socioeconomic status, categorized as $0–19 999, $20 000–34 999, $35 000–74 999, and ≥$75 000. A personal history of diabetes or gout was identified from the medical examination component, as was BMI, which was categorized as normal weight (18.0–24.9 kg/m^2), overweight (25.0–29.9 kg/m^2), and obese (≥30.0 kg/m^2).

2.5. Statistical analysis

We calculated the percent prevalence of a self-reported history of stone disease, using weights and design variables as reported by NHANES to account for the complex survey structure and produce estimates representative of the total civilian, noninstitutionalized US population. We also adjusted prevalence estimates using data from the 1990 census to account for population changes since previous NHANES items regarding kidney stones were queried. Overall, changes in estimates because of population adjustment were small; therefore, we report unadjusted figures except where otherwise noted. A logistic regression model was constructed to identify factors associated with prevalent stone disease and account for the complex survey structure. We used SAS v.9.2 (Cary, NC, USA) for all analyses. Results were considered statistically significant with two-sided $\alpha = 0.05$.

3. Results

A total of 12 110 participants responded to the question regarding a history of stone disease. The weighted overall prevalence of stone disease was 8.8% (95% confidence interval [CI], 8.1–9.5). After population adjustment, the prevalence of stone disease was 8.4% (95% CI, 7.7–9.0). Men were more likely to report a history of stone disease than women (Table 1). Overall, estimates of the prevalence of kidney stones decreased only slightly after population adjustment (Table 2); therefore, we report unadjusted prevalence estimates unless otherwise specified. In men and women, the weighted prevalence increased with age; these effects were observed among all racial/ethnic groups (Table 3). Similar results were seen for the secondary outcome of symptomatic stone disease, although the point estimates were slightly lower (Table 1).

Variation in the prevalence of stone disease existed among different racial/ethnic groups (Table 3). The prevalence of stone disease was highest among non-Hispanic white individuals, at 10.3% (95% CI, 9.4–11.1). Other ethnic/racial groups had a lower prevalence of stone disease. Among Hispanic individuals, the prevalence of kidney stones was 6.4%

(95% CI, 5.6–7.3), and among black, non-Hispanic individuals, the prevalence was 4.3% (95% CI, 3.4–5.3). This variation persisted after population adjustment.

BMI was associated with a history of stone disease (Fig. 1). The prevalence of kidney stones was higher among obese individuals (11.2% [95% CI, 10.0–12.3]) and overweight individuals (9.2% [95% CI, 7.9–10.5]) than among individuals of normal weight (6.1% [95% CI, 4.8–7.2]) ($p < 0.001$). For males and females, respondents at normal weight had the lowest prevalence of stone disease (males: 7.8% [95% CI, 5.4–10.1]; females: 4.4% [95% CI, 3.8–6.1]). Among obese males the prevalence of stone disease was 13.0% (95% CI, 11.0–15.1), and among obese females the prevalence was 9.6% (95% CI, 8.3–10.8).

Several respondent characteristics were associated with a history of kidney stones in the multivariable model (Table 4). The odds of kidney stones in females was approximately two-thirds that in men (odds ratio [OR]: 0.63 [95% CI, 0.52–0.74]; $p < 0.001$). Individuals reporting their race/ethnicity as Hispanic or black, non-Hispanic were also less likely to report a history of stone disease (Hispanic OR: 0.60 [95% CI, 0.49–0.73], $p < 0.001$; black, non-Hispanic OR: 0.37 [95% CI, 0.28–0.49], $p < 0.001$).

Socioeconomic status was also associated with a history of kidney stones. Those individuals with an annual household income ≤$19 999 were more likely than individuals earning >$75 000 annually to report a history of kidney stones (OR: 1.57 [95% CI, 1.17–2.09], $p = 0.002$). Individuals with an annual household income between $20 000 and $34 999 showed a similar increase in risk (OR: 1.65 [95% CI, 1.27–2.15], $p < 0.001$) compared with the high-income group.

Conditions associated the metabolic syndrome were also associated with a reported history of stone disease (Table 4). The odds of kidney stones were 1.55 times higher among obese participants than among individuals of normal weight (OR: 1.55 [95% CI, 1.25–1.94], $p < 0.001$). Respondents with a history of diabetes were also more likely to report kidney stones (OR: 1.59 [95% CI, 1.22–2.07], $p < 0.001$). A statistically significant relationship among dietary intake variables and history of kidney stones was observed only for high levels of sodium intake (data not shown). For these reasons, we did not include dietary intake variables in the final model (Table 4).

4. Discussion

In the first NHANES assessment of kidney stone disease since 1994, we found that 1 in 11 persons in the United States reports a history of stone disease. Among the highest-risk groups, the prevalence of stone disease approached one in five persons. These findings represent a marked increase in the prevalence of stone disease over the intervening 15 yr: In 1994, the reported prevalence of stone disease in the NHANES sample was only 5.2% (ie, 1 in 20 persons) [1]. This dramatic increase in the prevalence of stone disease persisted even after adjusting for the changes in the US population since NHANES III.

The changing epidemiology of kidney stone disease was not limited to one specific demographic cohort; increasing prevalence of stones was noted in all age, gender, and racial/ethnic groups, even on a population-adjusted basis. Among men, the overall prevalence of stone disease increased from 6.3% in 1988–1994 to a population-adjusted 10.3% in 2007–2010, representing a 63% relative increase in the prevalence of stone disease [1]. The change in prevalence of kidney stones was particularly dramatic in black, non-Hispanics (a 1.7% prevalence in 1988–1994 [1] compared with a population-adjusted 4.5% prevalence in 2007–2010, representing a relative increase of >150%). The relative prevalence increase among Hispanic individuals was also dramatic.

Recent claims-based analyses of health care utilization, particularly in the inpatient setting, have suggested a narrowing of the risk difference for stone disease between men and women [2,3]. Our data show that the overall prevalence of stone disease is 10.6% in males and 7.1% in females. At least two potential explanations exist for these apparently contradictory findings. First, these different findings could represent gender-based practice variation; that is, for reasons that are not illuminated by these data, men may be less likely to be treated as inpatients for stone disease. Alternately, our data are potentially consistent with the hypothesis that in the past, men were much more likely to form stones (represented by the large difference in prevalence between males and females aged ≥50 yr), but risks are currently more equal, as represented by the very similar prevalence of stone disease among males and females aged 20–49 yr. Because of the cross-sectional nature of the NHANES dataset, it is difficult to conclusively test this hypothesis. The NHANES dataset is specifically designed to estimate the prevalence of conditions in the US population and should be considered more reliable than claims-based utilization data for addressing questions of disease prevalence.

Prior analyses of NHANES data did not explore associations between markers of the metabolic syndrome (eg, overweight/obesity, diabetes) and the prevalence of stone disease. Since the last NHANES analysis, however, prospective data from three large cohorts clearly demonstrate an increasing risk of incident stone disease with obesity, weight gain, and other measures related to the metabolic syndrome [4,5]. Physiologically, obesity has been linked to increased renal excretion of calcium and uric acid, as well as increased urine acidity, all of which increase the risk of stone formation [8–13]. For these reasons, we investigated potential associations between obesity and a history of kidney stones. In multivariable models, we observed statistically significant relationships between a history of kidney stones and gout, diabetes, and obesity. Presuming obesity as a marker for the metabolic syndrome, which is linked epidemiologically and physiologically to risk of kidney stones, the epidemic of obesity in the United States is a likely explanation for the dramatic rise in the prevalence of stone disease. In our analysis, obesity was an equalizer between sexes; the prevalence of stone disease among obese women was higher than in normal-weight men. In addition, the rates of overweight/obesity are higher among black, non-Hispanic and Hispanic individuals than among white, non-Hispanic individuals [14]. These physiologic and epidemiologic data provide a plausible explanation for the observed changes in prevalence of stone disease in our sample compared with results from NHANES III [1].

Other factors may also contribute to the observed changes in stone disease prevalence. Mean average temperature is believed to be a major contributor to variation in geographic risk for stone disease [15,16]. Data from military deployments suggest that the onset of temperature-related changes in stone risk may occur within 90 d [17–20]. For these reasons, Brikowski and colleagues [21] speculate that temperature-related changes have contributed to, and may continue to exacerbate, the rising burden of stone disease.

Our findings should be considered in the context of important limitations. The rapid increase in radiologic imaging in the United States could translate into an increased diagnosis of asymptomatic kidney stones. To examine this possibility, we analyzed self-report of kidney stone passage as a secondary outcome. While the prevalence of stone passage was slightly lower than self-report of a history of kidney stones, these estimates still represent a marked increase in stone disease. The prevalence of stone disease increases with age; therefore, the aging of the US population would be expected to contribute to an overall increase in the prevalence of stone disease absent any other influences. However, population adjustment of our estimates suggested that changes in prevalence because of the aging of the population only partially explained the observed changes in prevalence.

Finally, our results should be considered in the context of the cross-sectional design of the NHANES instrument. While we explored nutritional intake (including moisture) in our multivariable models, we did not find important associations with a history of stone disease. This finding is consistent with the findings from the NHANES III analysis, in which significant associations between dietary factors and stone history were not observed [1]. Since the temporal relationship of participant diet at the time of NHANES and a past history of stone disease is unclear, it is not surprising that prospectively identified associations between diet and incident stone disease [4,5] were not observed in this cross-sectional design.

These limitations notwithstanding, our findings have important implications for treating patients with kidney stones in the United States. Continued increases in prevalence will presumably sustain recent increases in health care expenditures for treating patients with stone disease [2,22]. Currently, patient treatment is characterized primarily by surgical intervention for symptomatic stone events rather than management of the chronic metabolic condition that leads to recurrence in ≤50% of patients within 5 yr in a primarily working-age population [23]. Evidence from randomized controlled trials suggests that lifestyle and pharmacologic interventions are effective for secondary prevention of kidney stones [24–27]. The rapidly changing prevalence of kidney stones suggests that further efforts toward secondary prevention may be indicated.

5. Conclusions

The prevalence of kidney stones in the United States is markedly higher than when last measured in 1988–1994, and this increase is likely related to dietary and lifestyle factors. Given the temporary disability imposed by a symptomatic stone event, these findings have important implications for a disease that burdens a primarily working-age population. These findings suggest that the direct and indirect costs of kidney stones will continue to rise in the United States, and efforts should be directed toward ameliorating the burden of urinary stone disease.

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Take-home message

The prevalence of kidney stones in the United States has increased from 1 in 20 persons to 1 in 11 persons since 1994. This change is likely related to the rising prevalence of the metabolic syndrome in the US population.

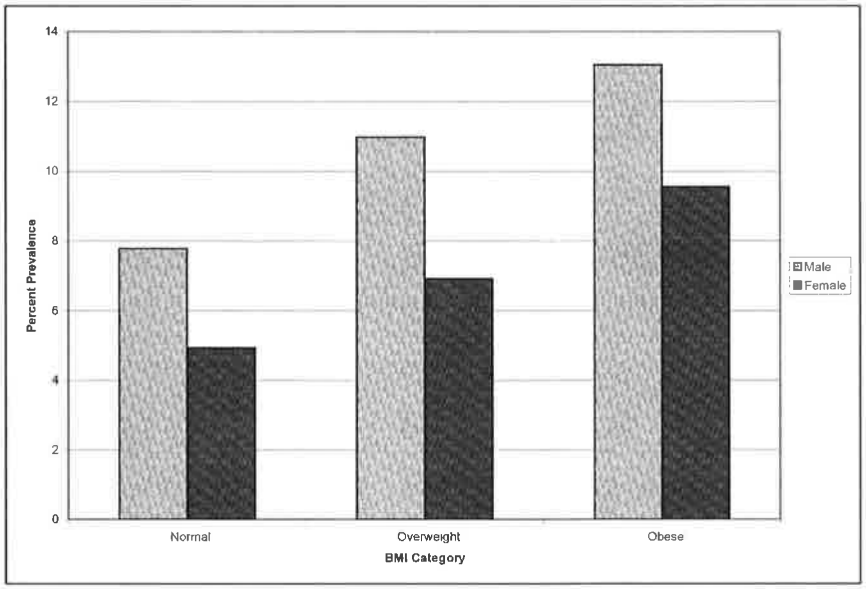

Fig. 1.
Weighted prevalence of stone disease by gender and body mass index (BMI) category.

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Table 1

Weighted (unadjusted) percent prevalence of stone disease by population characteristic

	History of kidney stones, % (95% CI)		History of passing at least one kidney stone, % (95% CI)	
Characteristic	Male	Female	Male	Female
Age group, yr				
20–29	3.4 (2.1–4.7)	3.4 (2.2–4.7)	3.3 (2.0–4.5)	2.5 (1.3–3.7)
30–39	6.9 (5.0–8.8)	5.9 (4.5–7.2)	6.5 (4.6–8.5)	5.0 (3.5–6.4)
40–49	9.8 (7.3–12.3)	7.6 (5.6–9.5)	8.1 (5.9–10.4)	6.4 (4.7–8.1)
50–59	13.1 (10.3–15.9)	8.1 (5.9–10.3)	11.1 (13.4–19.3)	6.9 (4.8–9.0)
60–69	19.1 (15.9–22.4)	9.4 (6.6–12.2)	16.3 (13.4–19.3)	8.4 (5.6–11.3)
70+	18.8 (16.5–21.0)	9.4 (7.5–11.3)	16.0 (13.8–18.3)	7.1 (5.5–8.8)
All ages	10.6 (9.4–11.9)	7.1 (6.4–7.8)	9.2 (8.1–10.3)	5.9 (5.2–6.6)

CI = confidence interval.

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Table 2

Unadjusted and population-adjusted percent prevalence of stone disease by population characteristic

	History of kidney stones, males		History of kidney stones, females	
Characteristic	**Unadjusted, % (95% CI)**	**Adjusted, % (95% CI)**	**Unadjusted, % (95% CI)**	**Adjusted, % (95% CI)**
All groups	10.6 (9.4–11.9)	10.3 (9.2–11.3)	7.1 (6.4–7.8)	6.7 (6.1–7.4)
Non-Hispanic, white	12.8 (11.3–14.3)	11.8 (10.4–13.2)	7.9 (7.0–8.8)	7.5 (6.7–8.4)
Hispanic	7.1 (5.7–8.4)	8.8 (7.4–10.2)	5.7 (4.6–6.9)	6.1 (4.9–7.3)
Non-Hispanic, black	4.5 (3.4–5.6)	4.8 (3.7–5.9)	4.2 (2.7–5.7)	4.2 (2.8–5.6)
Other race/multiracial	5.6 (2.5–8.8)	5.3 (2.2–8.5)	6.1 (2.7–9.6)	5.6 (2.4–8.8)

CI = confidence interval.

Table 3

Weighted (unadjusted) percent prevalence of stone disease by age and race

	History of kidney stones, % (95% CI)			History of passing at least one kidney stone, % (95% CI)		
	White (non-Hispanic)	Black (non-Hispanic)	Hispanic	White (non-Hispanic)	Black (non-Hispanic)	Hispanic
Age group, yr						
20–39	6.1 (4.5–7.7)	2.2 (1.3–3.0)	4.0 (3.0–5.0)	5.5 (4.0–7.0)	1.8 (0.87–2.7)	3.1 (2.2–4.0)
40–59	10.6 (8.9–12.3)	4.8 (3.0–6.6)	7.8 (5.9–9.6)	8.9 (7.2–10.6)	3.6 (2.1–5.1)	6.7 (5.0–8.5)
60–74	14.4 (12.4–16.3)	7.5 (5.5–9.5)	12.7 (10.5–14.8)	12.7 (10.8–14.6)	5.7 (3.9–7.4)	11.1 (8.8–13.5)
≥75	15.2 (12.9–17.6)	10.5 (4.2–16.8)	12.5 (6.9–18.0)	12.2 (9.8–14.6)	7.6 (2.9–12.4)	9.9 (5.1–14.7)
All ages	10.3 (9.4–11.1)	4.3 (3.4–5.2)	6.4 (5.6–7.3)	8.8 (7.9–9.7)	3.3 (2.5–4.2)	5.4 (4.4–6.3)

CI = confidence interval.

Table 4

Multivariable regression model predicting history of kidney stones

Characteristic	Odds ratio (95% CI)	*p* value
Age, yr		
20–39	1.00 (referent)	–
40–59	1.83 (1.37–2.45)	<0.001
≥60	2.18 (1.74–2.73)	<0.001
Female	0.63 (0.52–0.75)	<0.001
Race		
White, non-Hispanic	1.00 (referent)	–
Black, non-Hispanic	0.37 (0.28–0.49)	<0.001
Hispanic	0.60 (0.49–0.73)	<0.001
Other/multiracial	0.57 (0.37–0.89)	0.014
BMI category		
Normal	1.00 (referent)	–
Overweight	1.29 (0.96–1.72)	0.0875
Obese	1.55 (1.25–1.94)	<0.001
Household income, $		
≥75 000	1.00 (referent)	–
35 000–74 999	1.49 (1.16–1.92)	0.002
20 000–34 999	1.65 (1.27–2.15)	<0.001
0–19 999	1.57 (1.17–2.09)	0.002
Diabetes	1.59 (1.22–2.07)	<0.001
Gout	1.92 (1.44–2.56)	<0.001

CI = confidence interval; BMI = body mass index.

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Ren Fail. 2012;34(10):1348-54. doi: 10.3109/0886022X.2012.723777. Epub 2012 Sep 26.

Renal stone disease and obesity: what is important for urologists and nephrologists?

Ahmed MH[1], Ahmed HT, Khalil AA.

Author information

Abstract

Currently, obesity has reached an epidemic stage and represents a challenge for health authorities across the globe. Certainly, with emergence of obesity epidemic, we started to see an increase in the prevalence of chronic kidney disease (CKD) and nephrolithiasis. Interestingly, epidemiologic studies have shown that the incident stone risk increases with body mass index (BMI), and no further increase in risk is noticed when the BMI > 30 kg/m(2). Furthermore, metabolic syndrome and diabetes are also associated with an increase in the incidence of renal stones disease. The shared links between these metabolic disorders are insulin resistance. Furthermore, insulin resistance is thought to alter renal acid-base metabolism, resulting in a lower urine pH and increased risk of uric acid stone disease. Obesity is also associated with excess nutritional intake of lithogenic substances such as refined sugars, low fluid intake, calcium, oxalate, and purine-rich foods. Obesity is also associated with an increase in incidence of urinary tract infection. Recent reports suggested that renal stone disease carries risk of myocardial infarction, progression of CKD, and diabetes. Alarmingly, orlistat (obesity medication) and bariatric surgery are associated with hyperoxaluria and associated stone formation and even oxalate nephropathy. Certainly, the many health risks of obesity, including nephrolithiasis, will add more burden on urologists and nephrologists. Shockwave lithotripsy, percutaneous nephrolithotomy, and ureteroscopy are all safe procedures in obese individuals. Further research is urgently needed to address the pathophysiology and management of obesity-induced renal stones disease.

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Publication Types, MeSH Terms

LinkOut - more resources

Abstract

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Changing trends in the American diet and the rising prevalence of kidney stones.

De SK[1], Liu X[2], Monga M[3].

Author information

Abstract

OBJECTIVE: To evaluate the trends in the American diet over the last 40 years (1974-2010), during which time the National Health and Nutrition Examination Survey data set has documented an increase in stone prevalence from 3.8% to 8.8%.

MATERIALS AND METHODS: We used the National Health and Nutrition Examination Survey reported rates for stone disease (1974-2010) to compare the United States Department of Agriculture's food distribution data during the same period. Three data points for prevalence were used from the literature. We correlated these to changing lithogenic food distributions using linear models to interpolate annual changes in prevalence. Spearman correlations were performed ($P \leq .05$) using SAS 9.2 (SAS Institute, Cary, NC).

RESULTS: Increased total daily calories (rho, 0.96; $P < .001$), fat (rho, 0.79; $P < .001$), protein (rho, 0.85; $P < .001$), fruit (rho, 0.6; $P = .01$), and vegetables (rho, 0.73; $P < .001$) correlated strongly with increasing stone prevalence. Dark green vegetables, flour or cereal products, fish or shellfish, corn products (including high fructose corn syrup), and added sugars also showed strong correlations with stone prevalence. Citrus fruits were negatively correlated to stone disease (rho, -0.18; $P = .31$). Protein, fruits and vegetables, and added sugars actually decreased in proportion to daily caloric per capita increases.

CONCLUSION: Increases in caloric intake and several lithogenic foods correlate temporally with increasing stone prevalence. The nature of this relationship is difficult to determine from this data; although, clearly, American diets have changed over the last 4 decades.

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