**Appendix C. Table 1. Evidence table: Diet trials for recurrent nephrolithiasis**

| **Study/Region/**  **Funding Source** | **Inclusion/Exclusion Criteria** | **Patient Characteristics (expressed in means unless otherwise noted)** | **Baseline Stone Characteristics/Biochemistry** | **Intervention/**  **Duration** | **Study Quality** |
| --- | --- | --- | --- | --- | --- |
| Dussol 20081  Location: France  Funding Source: none stated | Inclusion Criteria:   * idiopathic calcium stone formers, regardless of the number of stone-forming episodes they had experienced * over age 18 and under 70   Exclusion Criteria:   * systemic disease (including primary hyperparathyroidism, sarcoidosis,vitamin D excess, bowel disease of any kind, renal tubular acidosis, primary hyperoxaluria or urinary tract infections). * hereditary or acquired anatomical disorders of the kidney or the urinary drainage system, except medullary sponge kidney | N=175  Age (yr): 44  Gender (Male %): 65  Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: BMI 24, weight 152 lbs  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): 1 mg/dL  Estimated GFR (ml/min/1.73m2): NR but creatinine clearance was 88 ml/min/1.73m2 Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: calcium  oxalate or a mixture of calcium phosphate and oxalate  Number of past stone episodes: NR but included patients regardless of number of past stone episodes.  Residual stones/ fragments: NR  Urine analysis:  Hypercalciuria 38%; Hypocitraturia NR; Hyperuricosuria NR; Hyperoxaluria 0%; Mixed NR;  No metabolic disorder; NR  Blood analysis: abnormalities were not stated | 1. Low animal protein diet, decrease intake of animal protein by limiting consumption of meat and fish to 3 servings per week and to not exceed 100 g/day of milk products. The target was to obtain a daily contribution of protein to energy of <13% (n=55).  2. High fiber diet, increase intake of fruits and vegetables and to substitute their usual cereals with whole grain dietary products in order to limit the increase in energy. The target was to obtain a 25-g/day increase in fiber intake.  Subjects were not instructed to exclude fruits and vegetables particularly rich in oxalate (n=60).  3. Controls (usual diet) (n=60)  Study dietician reinforced assigned dietary recommendations during every 4 month participant phone calls. | 1. Allocation Concealment:  adequate  2. Blinding: assessor 3. Intention to Treat Analysis: no 4. Withdrawals/Dropouts adequately described: yes  *Quality of harms reporting:*  No adverse events reported  : |

| **Appendix C. Table 1. Evidence table: Diet trials for recurrent nephrolithiasis (continued)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Study/Region/**  **Funding Source** | **Inclusion/Exclusion Criteria** | **Patient Characteristics (expressed in means unless otherwise noted)** | **Baseline Stone Characteristics/Biochemistry** | **Intervention/**  **Duration** | **Study Quality** |
|  |  |  |  | Followup period: 48 mos  Study withdrawals (%): 58 (n=102) at month 48  Assessment of compliance and adherence to treatment: 23.3% of high fiber group, 29.1% of low animal protein group, and 15% of controls withdrew because of the assigned diet (p=NS). In high fiber group, mean fiber intake increased from 17 g/day at baseline to 27 g/day at 1 year (p<0.01 vs baseline) and 23 g/day at 4 years (p<0.01 vs baseline). Mean fiber intake in control diet group did not change during follow-up. In low protein group, mean total protein intake increased from 84 g/day at baseline (57 g/day animal protein) to 68 g/day at 1 year (38 g/day animal protein), a level that was maintained at 4 years (p<0.001 versus baseline for both total protein and animal protein). By comparison, mean total protein intake in the control diet group was 84 g/day at baseline (55 g/day animal protein) and did not change during follow-up.  Setting (e.g., medicine, urology): Nephrology clinic  Follow up biochemical measures collected: (y/n): yes |  |
| Sarica 20062  Location: Turkey  Funding Source: none stated | Inclusion Criteria:   * renal stone subjects who underwent shock wave lithotripsy 3 months prior * calcium oxalate stones located in the renal pelvis without any urinary tract infection   Exclusion Criteria:   * other types of calculi * patient with previous stone disease history with stone passage * no metabolic abnormality (including hyperoxaluria, hypercalciuria, hyperuricosuria, and hyperparathyroidism) could be demonstrated, and no prior intervention | N=21 (of 45 total) stone free patients  Age (yr): 32(mean reported as 32 yrs)  Gender (Male %): 64  Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: NR  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): NR  Estimated GFR (ml/min/1.73m2): NR  Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: calcium oxalate 100%  Number of past stone episodes: single 100%, multiple 0%  Residual stones/ fragments: 53% by plain abdominal X-ray (including renal tomography) and kidney sonography (n=24)  Urine analysis:  Hypercalciuria 0%; Hypocitraturia NR;  Hyperuricosuria 0%;  Hyperoxaluria 0%; Mixed NR;  No metabolic disorder 100%  Blood analysis: no metabolic disorder 100% | 1. Forced fluid to achieve urinary output of >2.5 liters (n=12 (of 25) that were stone free)  2. No treatment  (n=9/20 that were stone free)  Followup period: 24-36 mos  Study withdrawals (%): 0  Assessment of compliance and adherence to treatment: Reported ‘good compliance’ in majority of participants in the intervention group  Setting (e.g., medicine, urology): none stated, authors noted to be affiliated with department of urology  Follow up biochemical measures collected: (y/n): no | 1. Allocation Concealment:  unclear, not specified  2. Blinding: none stated 3. Intention to Treat Analysis: yes 4. Withdrawals/Dropouts adequately described: none reported  *Quality of harms reporting:*  No adverse events reported |
| Borghi 20023  Location: Italy  Funding Source:  non-industry | Inclusion Criteria:   * idiopathic hypercalciuria (urinary calcium excretion, >300 mg per day on an unrestricted diet * recurrent formation of calcium oxalate stones (≥ 2 documented events   colic episodes with expulsion of stones or radiographic evidence of retained stones)  Exclusion Criteria:   * presence of condition commonly associated with calcium nephro-lithiasis (e.g., primary hyperparathyroidism, primary hyperoxaluria, enteric hyperoxaluria, bowel resection, inflammatory bowel disease, renal tubular acidosis, sarcoidosis, or sponge kidney) * previous visit to a stone disease center * current treatment for the prevention of recurrent stones except for the advice to increase water intake | N=120  Age (yr): 45  Gender (Male %): 100  Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: 171 lbs  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): 1.1  Estimated GFR (ml/min/1.73m2) NR but creatinine clearance was 126 ml/min Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: 0%  Pregnancy: NA  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: calcium oxalate 100%  Number of past stone episodes: Single 0%; Multiple 100%  Residual stones/ fragments: 27% by ultrasound and radiography  Urine analysis:  Hypercalciuria100%; Hypocitraturia NR;  Hyperuricosuria NR;  Hyperoxaluria 18% with “mild hyperoxaluria”;  Mixed NR;  No metabolic disorder 0%  Blood analysis: no metabolic disorder 0% | 1. Low calcium diet  (<10 mmol) (n= 60)  2.Low protein (<93 g) and low sodium (50 mmol) diet (n=60)  Both diets included daily increases in water intake to 2-3 liters.  Followup period: 60 mos  Study withdrawals (%): 14 (n=17)  Assessment of compliance and adherence to treatment: Mean urine volume increased from 1.1 L/d at 1 year to > 2.5L/d in intervention group compared to a maximum of 1.3L/d at 1 year in the control group  Setting (e.g., medicine, urology): not stated; authors affiliated with departments of clinical sciences and internal medicine and nephrology  Follow up biochemical measures collected: (y/n): yes | 1. Allocation Concealment:  adequate  2. Blinding: outcomes assessor only 3. Intention to Treat Analysis: yes 4. Withdrawals/Dropouts adequately described: yes  *Quality of harms reporting:*  1. Adverse events predefined: no  2. Adverse events reported for all participants: yes  3. Number of participants with adverse events reported for each study group: yes  4. Number of participants with each type of adverse event reported for each study group: yes  5. Number of participants that withdrew/lost to followup adequately described: yes |
| Di Silverio 20004  Location: Italy  Funding Source: none stated | Inclusion Criteria:   * received ESWL for idiopathic calcium kidney stone. * episodes of recurrence (3 recurrences within the last 4 years or 2 recurrences within the last 3 years). * free from clinically evident residual stones or fragments   Exclusion Criteria:   * patients with severe diabetes, gout or urinary infections. | N=384  Age (yr): 39  Gender (Male %): 60  Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: NR  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): NR  Estimated GFR (ml/min/1.73m2): NR  Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR (“severe” diabetes excluded)  History of HTN: NR  \*No data provided regarding what proportion of participants underwent ESWL in the prior 90 days versus more than 90 days before baseline. | Stone characteristics:  Stone type: calcium 100%  Number of past stone episodes: Single 0%; Multiple 100%  Residual stones/ fragments: 0% by X-ray and abdominal echographic studies  Urine analysis:  Hypercalciuria NR but mean baseline calcium levels were above the thresholds defined for hypercalciuria; Hypocitraturia NR; Hyperuricosuria NR; Hyperoxaluria NR; Mixed NR;  No metabolic disorder; NR  Blood analysis: none stated | 1. “Fiuggi water’” oligo-mineral water with a calcium content of 15 mg/I, 2 liters within a 24-hour period (n=192)  2. tap water with a calcium content between 55 and 130 mg/l, 2 liters within a 24-hour period (n=192)  A varied diet with a mean calcium content of 600 mg/day was prescribed for all patients.  Followup period: 19 mos  Study withdrawals (%): 0  Assessment of compliance and adherence to treatment: NR  Setting (e.g., medicine, urology): stone centers  Follow up biochemical measures collected: (y/n): yes | 1. Allocation Concealment:  unclear, not specified  2. Blinding: none stated 3. Intention to Treat Analysis: yes 4. Withdrawals/Dropouts adequately described: none reported  *Quality of harms reporting:*  No adverse events reported |
| Kocvara 19995  Location: Czech Republic  Funding Source:  non-industry | Inclusion Criteria:   * first idiopathic calcium kidney stone.   Exclusion Criteria:   * primary hyperpara-thyroidism * primary hyperoxaluria * renal tubular acidosis, with struvite, uric acid and cystine stones * medullary sponge disease | N=242 (number randomized per arm unclear)  Age (yr): range 18-72  Gender (Male %): 46 (those completing trial)  Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: NR  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): NR  Estimated GFR (ml/min/1.73m2): NR  Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: calcium 100% (primarily oxalate and some mixed with phosphate)  Number of past stone episodes: single 100%, multiple 0%  Residual stones/ fragments: 21% by ultrasound and radiography (n=43)  Urine analysis:  (Tailored diet only):  Hypercalciuria 67% ; Hypocitraturia 19%; Hyperuricosuria 27%;  Hyperoxaluria 18%;  Hypomagnesuria 9%;  Blood analysis (Tailored diet only):  Hyperuricemia 10%;  Hypomagnesemia 12% | Tailored diet:  1. Hypercalciuria: Restriction of animal proteins. Regular intake of calcium-rich food (0.75-1.0 g Ca) divided into small doses during the day  2. Hyperuricosuria/ hyperuricemia: Restriction of meat products to 80 g/day; 1-2 meatless days per week  3. Mild hyperoxaluria (up to 0.8 mmol/day): Firm restriction of oxalate-rich diet. Regular dairy intake in main meal. Lemons, increased fiber intake.  4. Magnesium deficiency: Increased fiber intake, especially bran. Regular intake of dairy products. High magnesium mineral water.  5. Hypocitraturia: Animal protein restriction. 1-2 lemons/day (orange juice in normal oxaluria). Increase fruit & vegetables (depending on oxaluria)  General diet recommendations  moderate intake (100–120 g) of animal proteins, restriction of oxalate-rich foods, an adequate calcium intake (0.75–1.0 g), increased fibre intake, and a moderate sodium intake.  (n= 94 completers)  Followup period: 36 mos  Study withdrawals (%):  14 (n=35)  Assessment of compliance and adherence to treatment: NR  Setting (e.g., medicine, urology): department of urology  Follow up biochemical measures collected: (y/n): yes | 1. Allocation Concealment:  unclear, not specified  2. Blinding: none stated 3. Intention to Treat Analysis: no 4. Withdrawals/Dropouts adequately described: no  *Quality of harms reporting:*  No adverse events reported |
| Borghi 19966  Location: Italy  Funding Source:  none stated | Inclusion Criteria:   * treatment for first idiopathic calcium kidney stone * absence of other retained calculi * absence of arterial hypertension or other metabolic pathology that requires regular dietary measures or drug therapy   Exclusion Criteria: none provided | N=220  Age (yr): 41  Gender (Male %): 67 (those completing trial)  Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: 154 lbs  BMI, weight, or percent with obesity: NR  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): NR  Estimated GFR (ml/min/1.73m2): NR  Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: calcium oxalate 100%  Past stone episodes: single 100%, multiple 0%  Residual stones/ fragments: 0% by plain abdominal x-ray, renal echography, and infusion excretory urography  Urine analysis:  Hypercalciuria NR; Hypocitraturia NR; Hyperuricosuria NR; Hyperoxaluria NR; Mixed NR;  No metabolic disorder; NR  Blood analysis: none stated | 1. Achieve urine volume >2 liters/day.  Urine volume to be measured every 2 months to ensure high volume (n=110)  2. No treatment (n=110)  Followup period: 60 mos  Study withdrawals (%): 10 (n=21)  Assessment of compliance and adherence to treatment: Reported that 3 participants withdrew as they did not want to comply with the diet. Also reported no difference in dietary compliance but did not give specific information  Setting (e.g., medicine, urology): stone center  Follow up biochemical measures collected: (y/n): yes | 1. Allocation Concealment:  unclear, not specified  2. Blinding: none stated 3. Intention to Treat Analysis: no 4. Withdrawals/Dropouts adequately described: no  *Quality of harms reporting:*  No adverse events reported |
| Hiatt 19967  Location: United States  Funding Source:  non-industry | Inclusion Criteria:   * documented single calcium oxalate kidney stone analyzed as ≥ 65 percent calcium oxalate * aged between 20-60 years * abdominal radiograph (x-ray film) with negative results within the previous 6 months.   Exclusion Criteria:   * known metabolic explanation for stone formation (e.g., renal tubular acidosis,   hyperparathyroidism,  acromegaly, Cushing's syndrome)   * chronic urosepsis, creatinine ≥1.8 mg/dl (137 unol/liter) * chronic small or large bowel disease | N=99  Age (yr): 43  Gender (Male %): 79  Race/Ethnicity (%): 77 white, 13 Asian, 5 Hispanic, 4 black  BMI, weight, or percent with obesity: BMI 25.5  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): NR  Estimated GFR (ml/min/1.73m2): NR  Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: calcium oxalate 100%  Number of past stone episodes: single 100%  Residual stones/ fragments: 0% by radiography  Urine analysis:  Hypercalciuria 18%; Hypocitraturia NR; Hyperuricosuria NR; Hyperoxaluria NR; Mixed NR;  No metabolic disorder; NR  Blood analysis: none stated | 1. Low animal protein and high fiber diet:  Decrease intake of animal protein (56 to 64 gm/day) and purine containing foods (75 mg/day); increase fruits, vegetables, and whole grains; and add 1/4 cup bran/day (n= 51, 50 included in study, 1 excluded post randomization)  2. Standard advice  instructed on fluid intake and calcium intake (n=51, 49 included in study 2 excluded post randomization)  Subjects advised to consume 2 servings of dairy products or 500 mg of calcium carbonate daily.  Followup period: 48 mos  Study withdrawals (%): 24 (n=24)  Assessment of compliance and adherence to treatment: Self reported reduction in dietary protein and purine at 6 mos in intervention group  Setting (medicine, urology): NR  Followup biochemical measures collected: (y/n): y | 1. Allocation Concealment:  unclear, not specified  2. Blinding: assesor 3. Intention to Treat Analysis: yes 4. Withdrawals/Dropouts adequately described: no  *Quality of harms reporting:*  No adverse events reported |
| Shuster 19928  Location: United States  Funding Source:  non-industry | Inclusion Criteria:   * male * aged 18-75 years * physician-confirmed urinary stone episode.   Exclusion Criteria:   * Soft drink consumption <160 mL daily | N=1009  Age (yr): 43  Gender (Male %): 100 Race/Ethnicity (%): NR  BMI, weight, or percent with obesity: NR  Previous bariatric surgery: NR Chronic kidney disease: NR  Serum creatinine (mg/dL): NR  Estimated GFR (ml/min/1.73m2): NR  Solitary kidney: NR  History of renal transplant: NR  Urinary tract anatomic abnormality: NR  Pregnancy: NR  History of CAD: NR  History of DM: NR  History of HTN: NR | Stone characteristics:  Stone type: All stone types  Number of past stone episodes: single 37% ;multiple 63%  Residual stones/ fragments: NR  Urine analysis:  Hypercalciuria NR; Hypocitraturia NR; Hyperuricosuria NR; Hyperoxaluria NR; Mixed NR;  No metabolic disorder; NR  Blood analysis: none stated | 1. Intervention group: Asked to refrain from soft drinks, educated about the link between soft drink consumption and stone formation  (n= 504)  2. No intervention (n=505)  Followup period: 36 mos  Study withdrawals (%): 7 (n=72)  Assessment of compliance and adherence to treatment: 43.1% at 6 months: defined as self reported consumption of < 680mL soda/week  Setting (e.g., medicine, urology): urology clinics  Follow up biochemical measures: (y/n): n | 1. Allocation Concealment:  unclear, not specified  2. Blinding: controls were blinded and telephone contact was masked for the treatment group 3. Intention to Treat Analysis: yes 4. Withdrawals/Dropouts adequately described: yes  *Quality of harms reporting:*  No adverse events reported |

**Abbreviations:** CAD = coronary artery disease; DM = diabetes mellitus; ESWL = extracorporeal shock wave lithotripsy; HTN = hypertension; NR = not reported; UTI = urinary tract infection