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国际中医技术操作规范 肠道灌洗技术治疗慢性肾脏病 3b~5 期

International standardized manipulations of Chinese medicine
Intestinal lavage technique for chronic kidney disease stages 3b~5

(草案, 以出版稿为准 Draft)

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前 言

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

主要起草单位：世界中医药学会联合会肾病专业委员会、广东省中医院、北京中医药大学东直门医院、南京中医药大学附属南京博大肾科医院

参与起草的单位：香港浸会大学中医学院、美国纽约长老会医院、University TUNKU ABDUL RAHMAN、北京智立医学技术股份有限公司、海南省中医院、北京中医院大学附属深圳医院、珠海市中医院、汕头市中医院、深圳市宝安区中医院（集团）、南方医科大学中西医结合医院、湖北省中医院、陕西省中医院

主要起草人：刘旭生、李靖、邹燕琴、王钢、邓丽丽、林静霞、王怡琨、刘汉娇。

参与起草人及审阅专家：

中 国：邹川、卢富华、王立新、包崑、吴一帆、张显龙、张腊、杨珂、林启展、赵代鑫、张蕾、苏国彬、谭秦湘、刘立昌、谈平、李泽文、唐晓娜、皮鹰、龚保文、揭西娜、周春姣、王荣荣、彭鹿、吴秀清、张洁婷、杜雪飞、汪玲珍、唐芳、傅立哲、刘枚芳、饶克瑯、聂晓莉、王宇、张姣、邓彩春、朱俊、沈辛宜、徐大基（中国香港）、罗仕妙、姜黎滨、郭志武、陆芳、乔延江、徐雯洁、刘红旭；

马来西亚：Judick Yap Wei Hoong；

美 国：李博安、Harry XU；

新 西 兰：王洪利；

英 国：江丹、汤淑兰；

意 大 利：Rinaldo Rinaldi、Sergio Bangrazi；

加 拿 大：吴滨江；

巴 西：Reginaldo de Carvalho Silva Filho；

日 本：韩涛；

瑞 典：魏巍；

斐 济：涂志辉；

泰 国：李曙杰。

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引 言

慢性肾脏病是全球重要的公共卫生问题，严重威胁着人类的生命健康和生活质量。因肾脏具有较强的代偿功能，处于慢性肾脏病初期的患者可无不适症状，进入 3b 期后，由于毒素在体内大量堆积，肾脏代偿功能下降，患者将会出现恶心呕吐、疲倦乏力、睡眠障碍、腰酸腰痛等不适症状，迫使患者就医。慢性肾脏病 3b~5 期非透析期患者，由于肾脏代谢异常，临床上主要表现为水、电解质和酸碱平衡失调，毒素蓄积而引起的一系列全身中毒症状。而当慢性肾脏病进展至终末期时，则需要进行透析或肾移植治疗，将产生更多的并发症、更高的死亡率及更重的医疗负担。

目前，现代医学对于延缓慢性肾脏病进展的治疗措施一般围绕治疗原发病、控制血压、蛋白尿等危险因素，以及对症处理等，方法较少，因此现在迫切需要发展更多能够有效治疗慢性肾脏病的手段。

中医认为，湿浊瘀毒内蕴几乎是所有慢性肾脏病患者的共同特征。肠道“受五脏浊气，为传化之府，此不能久留，输泻者也”，故称传导之官，因此“通腑泄浊”是贯穿慢性肾脏病治疗始终的重要方法。中药肠道灌洗正是基于“通腑泄浊”法而形成的一种中医特色疗法，目前随着临床证据的积累，该方法治疗慢性肾脏病 3b~5 期非透析患者的安全性及有效性也已得到初步验证。其治疗原理主要表现在两大方面：一是人体结肠黏膜的性质同半透膜，可调控肠腔液中电解质、活性物质等交换，使用中药结肠透析有助于协助肾脏排除体内毒素；二是慢性肾脏病患者存在肠道菌群失调，中药结肠透析可通过调节肠道微生态、改善免疫紊乱等作用，对慢性肾脏病 3b~5 期非透析患者起到良好的治疗效果。

目前尚未有针对慢性肾脏病 3b~5 期非透析期的肠道灌洗技术标准，但随着中药肠道灌洗技术的不断更新、改进、完善和发展，该技术愈发成熟，为更好地推广中药肠道灌洗在慢性肾脏病 3b~5 期非透析患者中的应用，规范中药肠道灌洗技术的操作规范，确保中药肠道灌洗技术的应用安全性与疗效，特制定本文件。

本文件是依据现有的研究证据、特定的方法制定出的声明性文件。在临床实践中，医师可参考本文件并结合患者具体情况进行个体化治疗。

国际中医技术规范

中药肠道灌洗治疗慢性肾脏病 3b~5 期

1 范围

本文件规定了肠道灌洗治疗慢性肾脏病 3b~5 期技术操作规范的术语和定义、器具要求、操作步骤、注意事项等内容。

本文件适用于对慢性肾脏病 3b~5 期患者进行肠道灌洗的操作。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

GB/T 20348-2006 中医基础理论术语

ISO 14971-2019 医疗装置 医疗装置风险管理的应用

3 术语和定义

下列术语和定义适用于本文件。

3.1

肠道灌洗

在结肠内建立一个有效的灌注、排泄的装置，利用结肠黏膜的半渗透性特点，通过中药透析液与肠黏膜组织毛细血管间的弥散、渗透和交换作用，清除体内代谢废物或毒素，纠正水、电解质、酸碱失衡的操作。

3.2

中药肠道灌洗液

由多种中药成分组成，用于肠道灌洗的中药液体制剂。

3.3

低位肠道灌洗

通过肛门插管至直肠处，注入适量药液的治疗方法。

3.4

高位肠道灌洗

通过肛门插管至降结肠处，将适量治疗药液通过肛门管注入大肠内部，充满整个肠道的治疗方法。

4 证候诊断

慢性肾脏病 3b~5 期的证候诊断见附录 A。

5 操作步骤

5.1 灌洗药物准备

5.1.1 灌洗药物选择

通过辨证论治，灌洗药物的选择见附录 A。

5.1.2 治疗方案

宜从本虚证、标实证、虚实夹杂证着手，结合脏腑机能的不及和病理产物蓄积太过，进行药物加减。医生、护士需在操作前对患者的耐受程度进行评估，根据评估结果确定灌入药物总量。

5.1.3 药物用量

5.1.3.1 低位肠道灌洗

根据患者辨证选用的灌洗中药，取去渣中药液 100ml，加入温水至 150~200ml 待用，倒入灌洗灌排装置或灌肠袋内，具体用量应根据患者耐受情况进行增减。

5.1.3.2 高位肠道灌洗

将灌洗药物和温水按照 1 : 4 的比例混合至 2000ml。

5.1.4 灌洗药物温度

灌入体内的灌洗药物温度应为 37.0℃~37.5℃，阳虚体寒者灌入体内药液温度为 38℃~39.5℃。

5.2 灌洗时间和频率

5.2.1 灌洗时间

- a) 17 时至 19 时为肾经循行时间，此时进行肠道灌洗治疗有利于提高药物作用。
- b) 选择两餐之间进行肠道灌洗治疗，可减轻人体不适感，并有利于药物吸收。

5.2.2 灌洗频率

- a) 低位肠道灌洗宜每日进行一次肠道灌洗治疗，具体灌洗天数宜根据患者实际情况及治疗效果决定。
- b) 高位肠道灌洗宜隔天进行一次高位肠道灌洗治疗，具体灌洗天数可根据患者实际情况及治疗效果决定。

5.3 灌洗体位

将灌肠袋携至患者床旁，挂在输液架上，液面离肛门 40~50cm。嘱患者左侧卧位，松开衣裤，将裤脱至大腿上 1/2 处，膝屈曲位。臀下用小枕垫高 10 cm，垫上治疗巾，注意保暖。弯盘置于臀缘，润滑肛门管前端。

5.4 灌洗流程

5.4.1 灌洗前评估

- a) 了解患者既往病史，当前主要症状及不适，过敏史等；
- b) 完善乙肝两对半、丙肝、梅毒、HIV 检验项目，排除相关传染病患者；
- c) 完善血浆凝血酶原时间、凝血酶时间、纤维蛋白原、纤维蛋白原降解产物、活化部分凝血活酶时间、D-二聚体检验项目，以评估患者机体凝血因子、抗凝系统及纤溶系统活性；
- d) 完善大便潜血检验项目，排除消化道出血可能；
- e) 对患者意识状态、体质及肛周皮肤情况进行判断，决定是否可以治疗，并与患者签署治疗知情同意书；
- f) 操作前进行肛门指检，排查可能的禁忌证；
- g) 评估患者心理状态以及对肠道灌洗的接受程度；
- h) 高位肠道灌洗作用位置深，可促进肠蠕动，增加药液作用部位和时间，加强排毒和改善便秘情况。低位肠道灌洗作用位置浅，用于排毒和治疗便秘。医护人员根据患者病情、排便情况、耐受程度选择肠道灌洗方式，可选择单一一种灌洗方式，也可两种方式相结合。
- i) 行高位肠道灌洗者，由医生根据患者情况决定是否需要进行肠镜检查。

5.4.2 灌洗前准备

- 5.4.2.1 嘱患者排空二便。
- 5.4.2.2 着装整洁，佩戴胸牌，洗手，戴口罩。
- 5.4.2.3 备齐用物，如中药液，治疗盘，灌洗灌排装置/一次性使用灌洗袋，水温计，弯盘，石蜡油，棉球，治疗巾，卫生纸，治疗本。
- 5.4.2.4 将物品携至床旁，向患者说明目的，取得配合，并用屏风遮挡患者。

5.4.3 灌洗器具选择

低位肠道灌洗宜用灌洗灌排装置作为灌洗药物灌入的推进器；高位肠道灌洗宜用肠道灌洗仪器作为灌洗药物灌入的推进器。

5.4.4 灌洗器具置入深度

- 5.4.4.1 低位肠道灌洗需将一次性使用肛门管经肛门置入肠道 15~20 cm。
- 5.4.4.2 高位肠道灌洗需将一次性使用肛门管经肛门置入肠道大于 20 cm。

5.4.5 灌洗步骤

- 5.4.5.1 选用合适的灌洗器具后，将灌洗药物灌入器具中。
- 5.4.5.2 用润滑液充分润滑其可置入肠道的肛门管部分。

5.4.5.3 具体操作步骤

(a) 低位肠道灌洗：将灌洗灌排装置排气，夹紧控制阀，润滑肛门管，左手分开臀部，润滑肛门周围，右手持肛门管插入，置入深度为 15~20 cm，稍停片刻，固定，缓慢打开控制阀，调整灌洗药液滴注速度 20~25 ml/min，同时询问患者对药液滴入的反应。8~10 min 药液滴完后，关闭控制阀，将肛门管缓缓拔出，用卫生纸轻轻按压肛门，将肛门管放入医疗垃圾桶，嘱患者卧位一小时。整理床单，清理用物，洗手，记录灌洗液量，滴入过程、时间，患者反应及签名。

(b) 高位肠道灌洗：将肠道灌洗仪器排气，润滑肛门管后轻轻插入患者肛门>20 cm，固定肛门管，确认灌洗药液温度适宜后，根据患者最大耐受程度将药液分次灌入患者体内，每次灌入后应将药液保留在体内 30 min 或以上（具体时长根据患者耐受程度增减），保留结束后待患者排干净后再进行下一次药液灌入，如此反复，直至药液全部灌完后缓慢拔出肛门管。将肛门管放入医疗垃圾桶，嘱患者卧位一小时。整理床单，清理用物，洗手，记录灌洗液量，滴入过程、时间，患者反应及签名。

6 适应证

- 6.1 处于慢性肾脏病 3b~4 期的患者。
- 6.2 因多种原因未进行血液透析、腹膜透析治疗的慢性肾脏病 4~5 期患者。
- 6.3 血液透析、腹膜透析适应症差、老年非透析期肾衰患者。
- 6.4 大便秘结者。
- 6.5 行腹膜透析治疗，但发生腹膜透析导管漂管并发症的患者。
- 6.6 慢性肾脏病以外的疾病，如慢性结肠炎、溃疡性结肠炎、肝性脑病、肝腹水、肝功能不全、肝肾综合征、重症肝炎、肝硬化等。

7 禁忌证

- 7.1 孕妇。
- 7.2 严重内痔、肛管黏膜炎症、有活动性出血的患者。
- 7.3 肛门括约肌松弛，难以顺利完成治疗者。
- 7.4 肛门、结肠、直肠手术后患者。
- 7.5 肠穿孔、肠坏死、腹膜炎、急性肠炎或消化道出血的患者。
- 7.6 人工肛门的患者。
- 7.7 未控制的严重心血管疾病、严重肝腹水、水肿的患者。
- 7.8 其他不适于肠道灌洗体位及要求的患者。
- 7.9 对肠道灌洗液或中药成分过敏的患者。

8 注意事项

- 8.1 操作过程中，应注意观察患者耐受度和神志，询问患者的感受，有无腹胀、腹痛及便意，当患者出现脉搏细数、面色苍白、出冷汗、剧烈腹痛、心慌等，应立即停止操作并报告医生。
- 8.2 药物注入完毕后，用卫生纸轻轻按揉片刻，包裹肛门管反折轻轻拔出。
- 8.3 灌洗后可使用 TDP 灯照射腹部，延长留腹时间，减轻腹痛反应。

8.4 灌洗治疗完成后，患者大便次数可能增加，应注意观察患者肛周皮肤情况，及时予以保护。

8.5 灌洗后重点观察患者腹痛及排便情况，并采用 Likert 五级评分法对患者出现的不适症状进行评分：如出现腹痛或便意，指导患者放松情绪、深呼吸，延长药液保留时间；观察患者心率、血压等生命体征，出现意外情况及时向主治医师汇报。

9 中药肠道灌洗相关并发症及处理措施

中药肠道灌洗相关并发症及处理措施见附录 B。

附录 A
(资料性)
证候诊断及推荐治疗方案

A.1 诊断原则

应用肠道灌洗方法治疗慢性肾衰时,需辨别本虚证与标实证,在临床上多为虚实夹杂证。

A.2 基础方

制大黄、煅牡蛎、蒲公英、土茯苓。此为肠道灌洗基础方,临床应用时可根据患者辨证分型进行药物加减。

A.3 辨证分型

A.3.1 本虚证

A.3.1.1 证候表现

表现为倦怠乏力,气短懒言。偏于肾气不足,可兼见腰膝酸软,夜尿频多,头晕耳鸣,舌淡,脉弱;偏于脾肾阳虚,可兼见畏寒肢冷,腰部冷痛,腹胀纳呆,舌淡胖,脉沉细或沉弱;偏于气阴两虚,可兼见口咽干燥,五心烦热,头晕肢乏,舌质淡或舌质红,苔少,脉细缓或细弱。

A.3.1.2 推荐方案

A.3.1.2.1 肾气不足

治法:补益肾气

推荐加减药物:桂枝,制附子,山萸肉,山药,熟地黄,黄芪,五味子,芡实,杜仲,牛膝等。

A.3.1.2.2 脾肾阳虚

治法:温补脾肾

推荐加减药物:制附子,人参,白术,炙甘草,干姜,桂枝,黄芪,肉苁蓉,肉桂,淫羊藿,巴戟天等。

A.3.1.2.3 气阴两虚

治法:益气养阴

推荐加减药物:党参,麦冬,五味子,黄芪,生地,女贞子,墨旱莲等。

A.3.2 标实证

A.3.2.1 证候表现

慢性肾衰的病理产物主要为浊毒瘀阻。偏于湿浊证,可兼见恶心呕吐,口中黏腻,舌苔

厚腻，脉象濡或弦滑；偏于湿热证，可兼见口苦口黏，大便不爽，舌苔黄腻，脉濡数，或脉弦滑数；偏于气滞证，可兼见暖气反酸，腹胀腹痛，肠鸣矢气，舌下络脉可曲张增粗，脉弦；偏于血瘀证，可兼见面色晦暗，舌质紫暗，肌肤甲错，脉涩或细涩。

A.3.2.2 推荐方案

A.3.2.2.1 湿浊证

治法：除湿化浊

推荐加减药物：法半夏，黄连，厚朴，木香，陈皮，芒硝，茯苓，积雪草，六月雪，草豆蔻，草果仁，藿香，佩兰等。

A.3.2.2.2 湿热证

治法：清热除湿

推荐加减药物：黄连，黄芩，栀子，藿香，茵陈，连翘，白豆蔻，白茅根，猫须草，石韦，金银花，青黛，黄柏，白头翁，槐花，白花蛇舌草，草薢等。

A.3.2.2.3 血瘀证

治法：活血化瘀

推荐加减药物：大黄，桃仁，红花，赤芍，当归，川芎，枳壳，虎杖，三七，牡丹皮，益母草，丹参，莪术，桂枝，泽兰，毛冬青，水蛭，地龙等。

A.3.2.2.4 气滞证

治法：行气通滞

推荐加减药物：柴胡，香附，枳实，赤芍，枳壳，木香，厚朴，莱菔子等。

A.3.3 虚实夹杂证

A.3.3.1 证候表现

慢性肾衰虚实夹杂证的症状因人而异，此时患者可能同时表现出上述本虚证和标实证症状，一般以脾肾亏虚，浊瘀内阻更为突出，可见食欲不振、恶心、呕吐、头痛、倦怠、乏力、困倦、口中异味、面色晦暗等症。偏于脾肾两虚，湿浊中阻者，舌淡，苔厚腻，脉沉弱；偏于脾肾两虚，浊毒内留者，舌苔厚腻，色晦暗。而浊毒日久伤津者，苔暗黄，厚燥少津；偏于气阴两虚，瘀血内阻者舌暗红或紫暗，苔少，脉细涩。

A.3.3.2 推荐方案

A.3.3.2.1 脾肾两虚，湿浊中阻

治法：补脾益肾，除湿化浊

推荐加减药物：黄芪，菟丝子，党参，白术，山药，黄积雪草，厚朴，五味子，芡实，杜仲，砂仁，六月雪，陈皮，藿香，佩兰等。

A.3.3.2.2 脾肾两虚，浊毒内留

治法：补脾益肾，化浊泄毒

推荐加减药物：黄芪，菟丝子，党参，白术，山药，枳实，厚朴，白花蛇舌草，五味子，

芡实，黄芩，黄连，藿香，佩兰，茵陈，薏苡仁，半枝莲等。

A.3.3.2.3 气阴两虚，瘀血内阻

治法：益气养阴，活血化瘀

推荐加减药物：党参，麦冬，五味子，桂枝，桃仁，炙甘草，黄芪，生地，女贞子，墨旱莲，川芎，当归，生地，红花，赤芍，丹参，芒硝等。

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附录 B
(规范性)
中药肠道灌洗相关并发症及处理措施

B.1 肠道黏膜损伤

B.1.1 临床表现

肛门疼痛，排便时加剧，伴局部压痛；损伤严重时可见肛门外出血或粪便带血丝；甚至排便困难。

B.1.2 处理措施

B.1.2.1 患者肛门疼痛时，暂停灌洗；

B.1.2.2 疼痛轻者，嘱全身放松，帮助其分散注意力，减轻疼痛。疼痛剧烈者，立即予以对症处理，一旦发生肠出血按肠出血处理。

B.2 肠出血

B.2.1 临床表现

肛门滴血或排便带有血丝、血凝块。

B.2.2 处理措施

B.2.2.1 患者一旦出现脉搏快、面色苍白、大汗、剧烈腹痛、心慌气促，可能发生了肠道剧烈痉挛或出血，应立即停止灌洗并嘱患者平卧。

B.2.2.2 严密观察患者的生命体征以及腹部情况，如发生肠穿孔、肠破裂，按肠穿孔、肠破裂处理。

B.2.2.3 建立静脉输液通道，根据病情遵医嘱应用相应的止血药物或局部治疗。

B.3 肠穿孔、肠破裂

B.3.1 临床表现

灌洗过程中患者突然觉得腹胀、腹痛，查体腹部有压痛或反跳痛。腹部 B 超可发现腹腔积液。

B.3.2 处理措施

B.3.2.1 立即停止灌洗并使患者平卧，同时进行抢救；

B.3.2.2 立即建立静脉通道，积极完善术前准备，尽早手术；

B.3.2.3 给予吸氧、心电监护，严密观察患者的生命体征。

B.4 水中毒、电解质紊乱

B.4.1 临床表现

B.4.1.1 水中毒者早期表现为烦躁不安，继而嗜睡、抽搐、昏迷，查体可见球结膜水肿；

- B.4.1.2 脱水患者诉口渴，查体皮肤干燥、心动过速、血压下降、小便减少、尿色加深；
- B.4.1.3 低钾血症者软弱无力、腹胀、肠鸣音减弱、腱反射迟钝或消失，可出现心律失常，心电图可见 ST-T 改变和出现 U 波。

B.4.2 处理措施

- B.4.2.1 一旦发生水中毒、电解质紊乱，立即停止灌洗并使患者平卧，同时报告医生，进行抢救；
- B.4.2.2 立即建立两路静脉通道，为患者输注林格液体及 4%氯化钠注射液，以补充电解质，运用甘露醇、呋塞米（速尿）以减轻脑水中毒；
- B.4.2.3 给予镇静剂，以减轻患者抽搐；
- B.4.2.4 给予胃肠减压，以减轻患者腹胀；
- B.4.2.5 给予吸氧、心电监护，严密观察患者生命体征的变化；
- B.4.2.6 密切观察尿量和尿比重。同时向患者解释和安慰患者家属，保持镇静。

B.5 虚脱

B.5.1 临床表现

患者突感恶心、头晕、面色苍白。全身出冷汗甚至晕厥。

B.5.2 处理措施

立即停止灌洗并助患者平卧、保暖，一般休息片刻后可缓解恢复正常；如与饥饿有关，清醒后给予口服糖水等；如休息片刻后未缓解，给其吸氧，必要时静脉注射葡萄糖等，症状可逐渐缓解。

B.6 肠道感染

B.6.1 临床表现

腹痛，大便次数增多，大便的量、颜色、形状有所改变。

B.6.2 处理措施

- B.6.2.1 根据大便化验结果和致病微生物情况，选择适合的抗菌药物；
- B.6.2.2 观察大便的量、颜色、性状等的变化并记录；
- B.6.2.3 根据医嘱应用抗菌药物。

B.7 大便失禁

B.7.1 临床表现

大便不由自主地由肛门排出。

B.7.2 处理措施

- B.7.2.1 已发生大便失禁者，床上铺橡胶（或塑料）单和中单或一次性尿布，每次便后用温水洗净肛门周围及臀部皮肤，保持皮肤干燥；

B.7.2.2 必要时，肛门周围涂搽软膏以保护皮肤，避免破损感染。

B.8 肛周皮肤擦伤

B.8.1 临床表现

肛周皮肤破溃，红肿。

B.8.2 处理措施

B.8.2.1 皮肤破溃时可用 TDP 灯照射治疗，每天 2 次，每次 15~30 分钟；

B.8.2.2 以外科无菌换药法处理伤口。

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Preface

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Main Drafting Units: Kidney Disease Professional Committee (World Federation of Chinese Medicine Societies), Guangdong Provincial Hospital of Traditional Chinese Medicine, Beijing Dongzhimen Hospital (Beijing University of Chinese Medicine), Nanjing Boai Kidney Hospital (Nanjing University of Traditional Chinese Medicine)

Participating Drafting Units: Hong Kong Baptist University School of Chinese Medicine, New York Presbyterian Hospital, University TUNKU ABDUL RAHMAN, Beijing Zhili Medical Technology Co., Ltd., Hainan Provincial Hospital of Traditional Chinese Medicine, Shenzhen Hospital (Beijing University of Chinese Medicine), Zhuhai Hospital of Traditional Chinese Medicine, Shantou Hospital of Traditional Chinese Medicine, Shenzhen Bao'an District Traditional Chinese Medicine Hospital (Group), Southern Medical University Integrated Traditional Chinese and Western Medicine Hospital, Hubei Provincial Hospital of Traditional Chinese Medicine, Shaanxi Provincial Hospital of Traditional Chinese Medicine

Main Drafters: Xusheng Liu, Jing Li, Yanqin Zou, Gang Wang, Lili Deng, Jingxia Lin, Yikun Wang, Hanjiao Liu

Participating Drafters:

China: Chuan Zou, Fuhua Lu, Lixin Wang, Kun Bao, Yifan Wu, La Zhang, Xianlong Zhang, Ke Yang, Qizhan Lin, Daixin Zhao, Lei Zhang, Guobin Su, Qinxiang Tan, Lichang Liu, Ping Tan, Zewen Li, Xiaona Tang, Ying Pi, Baowen Gong, Xina Jie, Chunjiao Zhou, Rongrong Wang, Lu Peng, Xiuqing Wu, Jieting Zhang, Xuefei Du, Lingzhen Wang, Fang Tang, Lizhe Fu, Meifang Liu, Kelang Rao, Xiaoli Nie, Yu Wang, Jiao Zhang, Caichun Deng, Jun Zhu, Xinyi Shen, Daji Xu (Hong Kong, China), Shimiao Luo, Libin Jiang, Zhiwu Guo, Fang Lu, Yanjiang Qiao, Wenjie Xu, Hongxu Liu;

Malaysia: Judick Yap Wei Hoong;

United States: Bo'an Li, Harry Xu;

New Zealand: Hongli Wang;

United Kingdom of Great Britain and Northern Ireland: Dan Jiang, Shulan Tang;

Italy: Rinaldo Rinaldi, Sergio Bangrazi;

Canada: Jiangbin Wu;

Brazil: Reginaldo de Carvalho Silva Filho;

Japan: Tao Han;

Sweden: Wei Wei;

Fiji: Zhihui Tu;

Thailand: Shujie Li.

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Introduction

Chronic kidney disease (CKD) is a significant global public health challenge, posing a severe threat to human life, health, and overall well-being. In the early CKD stage, patients often remain asymptomatic due to the kidneys' compensatory abilities. However, as the disease progresses to stage 3b and beyond, the accumulation of toxins leads to a decline in kidney function, manifesting as symptoms such as nausea, fatigue, sleep disturbance and lower back pain, prompting patients to seek medical attention. During CKD stages 3b-5, non-dialysis patients experience significant metabolic abnormalities, resulting in systemic manifestations of electrolyte imbalances, acid-base disturbances, and toxin-related toxicity.

When CKD advances to end-stage kidney disease (ESKD), patients require dialysis or kidney transplant, leading to more complications, higher mortality rates, and increased healthcare costs. Current medical interventions for slowing CKD progression primarily focus on treating underlying causes, controlling risk factors like blood pressure and proteinuria, and symptomatic relief. Therefore, there is an urgent need to explore additional effective treatments for CKD.

Traditional Chinese medicine suggests that most CKD patients share a common feature of dampness, turbidity, stagnation, and toxin accumulation. The gastrointestinal tract, regarded as the "conductor" of transmitting and transforming energies between the internal organs, plays a vital role in CKD treatment. Colonic irrigation with Chinese herbal medicine is a unique therapy rooted in the concept of "clearing the intestines to remove turbidity." A growing body of clinical evidence has preliminarily validated the safety and efficacy of this approach for the treatment of CKD stages 3b-5 in non-dialysis patients.

The therapy's underlying principles focus on two main concepts: first, the mucosa of the human colon is similar to a semipermeable membrane, enabling the regulation of electrolytes and active substances within the colonic cavity. The use of Chinese herbal colonic irrigation assists in toxin elimination, supporting the kidneys. Second, CKD patients often exhibit disrupted gut microbiota. Colonic irrigation with Chinese herbal medicine can regulate gut microbiota and alleviate immune imbalances, yielding favorable treatment outcomes for non-dialysis CKD stages 3b-5 patients.

Although standardized technical guidelines for colonic irrigation in non-dialysis CKD stages 3b-5 patients have yet to be established, the maturation and development of this therapy, combined with its continuous improvement, necessitate the creation of operational standards for the application of Chinese herbal colonic irrigation. This document is formulated to promote the use of Chinese herbal colonic irrigation among CKD stage 3b-5 non-dialysis patients, ensuring its safety and effectiveness.

International standardized manipulations of Chinese medicine

Intestinal lavage technique for chronic kidney disease stages 3b~5

1 Scope

This document specifies the terms and definitions, equipment requirements, operating procedures, and precautions for the technical operation specifications of intestinal lavage for treating stage 3b-5 chronic kidney disease.

It applies to the operation of intestinal lavage for patients with stage 3b-5 chronic kidney disease.

2 Normative references

The following documents contain indispensable provisions along with normative references. For dated references, only the edition and date cited applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 20348-2006 Traditional Chinese Medicine Basic Theory Terminology

ISO 14971-2019 Medical Devices Application of Risk Management to Medical Devices

3 Terms and definitions

The following terms and definitions apply to this document:

3.1

Intestinal lavage

establishment of an effective perfusion and excretion device in the colon is an operation intended to remove metabolic waste or toxins from the body and correct water, electrolyte, and acid-base imbalances. It involves using the semi-permeable characteristics of the colonic mucosa, and is accomplished through the diffusion, osmosis, and exchange between the Chinese herbal dialysate and the capillaries in the colonic mucosal tissue.

3.2

Chinese herbal medicine intestinal lavage solution

a liquid preparation of Chinese herbal medicine used for intestinal lavage.

3.3

Low-level intestinal lavage

a treatment method in which the appropriate amount of medicinal liquid is injected through a rectal catheter into the rectum.

3.4

High-level intestinal lavage

a treatment method in which the appropriate treatment liquid is injected through an anal tube into the descending colon, filling the entire small intestine.

4 Syndrome diagnosis

The syndrome diagnosis of stage 3b-5 chronic kidney disease is given in Annex A.

5 Operating procedures

5.1 Lavage drug preparation

5.1.1 Lavage drug selection

Lavage drug selection is based on dialectical treatment, as outlined in Annex A.

5.1.2 Treatment plan

It is advisable to start with virtual, true, or mixed syndromes. Adjust medication based on the inadequacy of organ function and excessive accumulation of pathological products. Doctors and nurses should assess the patient's tolerance before the procedure and determine the total amount of medication to be administered based on the assessment results.

5.1.3 Medication dosage

5.1.3.1 Low-level intestinal lavage

Use the residue-free Chinese herbal medicine liquid chosen by the Doctor according to patients' pattern, and add 150-200 mL of warm water. Pour the solution into the lavage and drain the device or the enema bag. Adjust the amount based on the patient's tolerance.

5.1.3.2 High-level intestinal lavage

Mix the lavage medication and warm water at a 1:4 ratio for a total of 2,000 mL.

5.1.4 Medication temperature

The temperature of the lavage medication administered should be 37.0°C-37.5°C. For those with Yang deficiency and a cold body, the temperature of the

administered medication should be 38°C-39.5°C.

5.2 Lavage time and frequency

5.2.1 Lavage time

- a) The kidney meridian circulates between 17:00 and 19:00, and performing intestinal lavage treatment at this time is conducive to boosting the medication's effects.
- b) Performing intestinal lavage treatment between meals alleviates discomfort and improves drug absorption.

5.2.2 Lavage frequency

- a) Low-Level Intestinal Lavage: Perform intestinal lavage treatment once per day, and determine the number of treatment days based on the patient's actual conditions and treatment effectiveness.
- b) High-Level Intestinal Lavage: High-level intestinal lavage treatment should be performed every other day, and the specific number of days for treatment can be determined based on the patient's actual conditions and treatment effectiveness.

5.3 Lavage position

Bring the enema bag to the patient's bedside, hang it on an infusion stand, and position the liquid level 40-50 cm away from the anus. Instruct the patient to lie on the left side, loosen their clothing, pull their pants up to their thighs, and flex their knees. Place a small pillow under their buttocks, elevating them by 10 cm, and put a treatment towel on top, ensuring warmth. Place a bent plate at the buttocks, and lubricate the front end of the rectal tube.

5.4 Lavage procedure

5.4.1 Pre-lavage assessment

- a) Obtain the patient's medical history, current main symptoms, discomfort, and allergy history.
- b) Complete hepatitis B, hepatitis C, syphilis, and HIV test items to exclude any patients with related infectious diseases.
- c) Complete blood plasma coagulation prothrombin time, coagulation time, fibrinogen, fibrinogen degradation product, activated partial thromboplastin time, and D-dimer test items to evaluate the patient's coagulation factors, anticoagulant system, and fibrinolysis system activity.
- d) Complete fecal occult blood test items to exclude the possibility of gastrointestinal bleeding.

e) Assess the patient's consciousness, physical condition, and perianal skin condition to determine if treatment is appropriate, and obtain the patient's informed consent for treatment.

f) Perform a digital rectal examination before the procedure to rule out any contraindications.

g) Assess the patient's psychological status and their tolerance of intestinal lavage.

h) High-level intestinal lavage acts deep, promotes intestinal peristalsis, increases the size and duration of drug action, promotes detoxification, and improves constipation. Low-level intestinal lavage is shallow and used for detoxification and constipation treatment. Medical staff selects the intestinal lavage method based on the patient's condition, bowel movements, and tolerance, which can be a single method or a combination of two methods.

i.) If performing high-level intestinal lavage, the doctor will decide whether a colonoscopy is needed based on the patient's condition.

5.4.2 Pre-lavage preparation

5.4.2.1 Instruct the patient to empty their bowels.

5.4.2.2 Dress professionally, wear an identification badge, wash hands, and wear a mask.

5.4.2.3 Prepare the necessary items, such as Chinese herbal liquid, treatment tray, lavage, drainage device/disposable lavage bag, thermometer, curved pan, paraffin oil, cotton balls, treatment towels, tissue paper, and medical records.

5.4.2.4 Bring the items to the patient's bedside, explain the purpose to the patient, gain their cooperation, and use a screen to shield the patient.

5.4.3 Selecting lavage equipment

For low-level intestinal lavage, a lavage and drainage device is suitable as the propeller for introducing lavage medication. For high-level intestinal lavage, a colon irrigator instrument is suitable as the propeller for introducing lavage medication.

5.4.4 Instrument placement depth

5.4.4.1 For low-level intestinal lavage, insert the disposable anal tube through the anus into the large intestine at a depth of 15-20 cm.

5.4.4.2 For high-level intestinal lavage, insert the disposable anal tube through the anus into the large intestine at a depth of at least 20 cm.

5.4.5 Lavage steps

5.4.5.1 After selecting the appropriate lavage equipment, introduce the lavage medication into the equipment.

5.4.5.2 Lubricate the anal tube to be inserted into the intestine with a lubricating agent.

5.4.5.3 Specific steps are listed as below:

(a) For low-level intestinal lavage: release the air from the lavage and drainage device, close the control valve, lubricate the anal tube, separate the buttocks with the left hand, lubricate around the anus, insert the anal tube with the right hand to a depth of 15-20 cm, pause briefly, secure it, slowly open the control valve, adjust the medication drip rate to 20-25 mL/min, and inquire about the patient's reaction to the medication entering. After 8-10 minutes, close the control valve, gently remove the anal tube, gently press the anus with tissue paper, dispose of the anal tube in a medical waste bin, and instruct the patient to lie down for an hour. Organize the patient's bed, clean the items, wash hands, record the lavage fluid volume, dripping process, time, and patient reactions, and obtain signatures.

(b) For high-level intestinal lavage: release the air from the colon irrigator instrument, lubricate the anal tube, gently insert it into the patient's rectum at least 20 cm, secure the anal tube, confirm that the lavage medication temperature is appropriate, and introduce the medication into the patient in increments based on the patient's maximum tolerance. Each introduction should be retained in the patient's body for at least 30 minutes (adjust the specific duration based on the patient's tolerance), and after retention, introduce the next medication only after the patient has voided the infused medication. Repeat this process until all the medication has been introduced, and slowly remove the anal tube. Place the anal tube in the medical waste bin and instruct the patient to lie down for an hour. Organize the patient's bed, clean the items, wash hands, record the lavage fluid volume, the dripping process, time, and patient reactions, and obtain signatures.

6 Indications

6.1 Patients in stages 3b-4 of chronic kidney disease.

6.2 Patients in stages 4-5 of chronic kidney disease who have not undergone hemodialysis or peritoneal dialysis treatment, for various reasons.

6.3 Patients with poor indications for hemodialysis or peritoneal dialysis, elderly non-dialysis patients with renal failure.

6.4 Patients with constipation.

6.5 Patients undergoing peritoneal dialysis but experiencing complications related to the peritoneal dialysis catheter.

6.6 Diseases other than chronic kidney disease, such as chronic colitis, ulcerative colitis, hepatic encephalopathy, ascites, liver dysfunction, hepatorenal syndrome, severe hepatitis, and cirrhosis.

7 Contraindications

7.1 Pregnant women.

7.2 Patients with severe internal hemorrhoids, anal mucosal inflammation, or active bleeding.

7.3 Patients with lax anal sphincter muscles may have difficulty completing the treatment.

7.4 Patients after anal, colon, or rectal surgery.

7.5 Patients with intestinal perforation, intestinal necrosis, peritonitis, acute enteritis, or gastrointestinal bleeding.

7.6 Patients with an artificial anus.

7.7 Patients with uncontrolled severe cardiovascular diseases, severe ascites, or edema.

7.8 Other patients who are not suitable for intestinal lavage positions and requirements.

7.9 Patients who are allergic to lavage fluid or Chinese herbal ingredients.

8. Precautions

8.1 During the procedure, observe the patient's tolerance and consciousness, and ask about their sensations, any presence of abdominal distension, abdominal pain, or bowel urges. If the patient experiences a rapid pulse, pallor, cold sweat, severe abdominal pain, palpitations, etc., immediately stop the procedure and report this to the doctor.

8.2 After drug administration, gently massage the anus with tissue paper, and remove the anal tube by gently folding it.

8.3 After lavage, TDP lamps can be used to irradiate the abdomen, extending the retention time, and reducing abdominal pain reactions.

8.4 After lavage treatment, the patient may experience an increase in bowel movements. Observe the patient's perianal skin condition and provide protection when necessary.

8.5 After lavage, it is crucial to closely monitor the patient's abdominal pain and bowel movements. Employ a Likert five-point scoring system to assess any discomfort or symptoms experienced by the patient. In the case of abdominal pain or a strong urge for a bowel movement, the patient should be guided to

relax, practice deep breathing, and prolong the retention time of the medicinal solution. Vital signs such as heart rate and blood pressure should be observed, and any unexpected developments should be promptly reported to the attending physician.

9 Complications related to chinese medicine colonic lavage and corresponding management

For complications associated with traditional Chinese medicine colonic lavage and the appropriate measures for handling them, please refer to Annex B.

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Annex A (Informational)

Pattern differentiation diagnosis and recommended treatment plans

A.1 Diagnosis principles

When treating chronic renal failure with the intestinal irrigation method, it is necessary to distinguish between primary deficiency patterns (本虚证) and secondary excess patterns (标实证). In clinical practice, these patterns are often confused for one another.

A.2 Basic formula

Prepared rhubarb, processed oyster shells, dandelion, and poria. This is the basic formula for intestinal irrigation, and it can be modified according to the patient's pattern differentiation.

A.3 Pattern differentiation

A.3.1 Primary deficiency pattern

A.3.1.1 Symptoms

Symptoms include fatigue, shortness of breath, and a lack of desire to speak. If the symptoms tend toward kidney qi deficiency, there may also be soreness and weakness in the lower back and knees, frequent nighttime urination, dizziness, and tinnitus. If the symptoms tend toward spleen and kidney yang deficiency, there may also be an aversion to cold, cold limbs, cold pain in the waist, abdominal distention, or poor appetite. If the symptoms tend toward qi and yin deficiency, there may also be symptoms such as dry mouth and throat, restlessness, dizziness, and limb weakness.

A.3.1.2 Recommended Treatment

A.3.1.2.1 Kidney qi deficiency

Treatment principle: Tonify kidney qi.

Recommended modified herbs: guizhi, processed fuzi, shanyurou, shanyao, shoudihuang, huangqi, wuweizi, danshi, duzhong, niuxi.

A.3.1.2.2 Spleen and kidney yang deficiency

Treatment principle: Warm and tonify the spleen and kidneys

Recommended modified herbs: Processed fuzi, renshen, baizhu, zhigancao, ganjiang, guizhi, huangqi, rourong, rougui, yinyanghuo, bajitian

A.3.1.2.3 Qi and yin deficiency

Treatment principle: Tonify qi and nourish yin

Recommended modified herbs: dangshen, maidong, wuweizi, huangqi, shengdi, nüzhenzi, mo hanlian

A.3.2 Secondary excess pattern

A.3.2.1 Symptoms

The main pathological product of chronic kidney failure is turbid toxins and blood stasis. If the symptoms tend toward damp turbidity, there may also be symptoms such as nausea, vomiting, dry mouth, and a thick tongue coating. If the symptoms tend toward damp heat, there may also be bitterness in the mouth, dry mouth, discomfort in defecation, and/or a yellow tongue coating. If the symptoms tend toward qi stagnation, there may also be belching, acid regurgitation, abdominal distension, or noisy intestines. If the symptoms tend toward blood stasis, there may also be symptoms such as a dull complexion, purple tongue, and/or nail abnormalities.

A.3.2.2 Recommended treatment

A.3.2.2.1 Dampness and turbidity

Treatment principle: Eliminate dampness and transform turbidity.

Recommended modified herbs: banxia, huanglian, houpou, muxiang, chenpi, mangxiao, fuling, jixuecao, liuyuexue, caodoukou, caoguoren, huoxiang, peilan

A.3.2.2.2 Damp-heat

Treatment principle: Clear heat and eliminate dampness.

Recommended modified herbs: huanglian, huangqin, zhizi, huoxiang, yinchén, lianqiao, baidoukou, baimaogen, maoxucao, shiwei, jinyinhua, qingdai, huangbo, baitouweng, huaihuasheshecao, yiyiren.

A.3.2.2.3 Blood stasis

Treatment principle: Activate blood circulation and resolve stasis.

Recommended modified herbs: dahuang, taoren, honghua, chishao, danggui, chuanxiong, zhike, huozhang, sanqi, mupi, yimucao, danshen, ezhuru, guizhi, zelan, maodongqing, shuizhi, dilong.

A.3.2.2.4 Qi stagnation

Treatment principle: Promote qi flow and relieve stagnation.

Recommended modified herbs: chahu, xiangfu, zhishi, chishao, zhike, muxiang, houpou, laifuzi

A.3.3 Mixed deficiency-excess pattern

A.3.3.1 Symptoms

Symptoms of mixed deficiency-excess patterns in chronic kidney failure can vary from person to person. Patients may simultaneously exhibit symptoms of the primary deficiency pattern and secondary excess pattern described above. Generally, the dominant factors are spleen-kidney deficiency and the presence of turbid stasis. This may result in symptoms such as decreased appetite, nausea, vomiting, headaches, fatigue, weakness, drowsiness, a foul taste in the mouth, and/or a darkened complexion.

A.3.3.2 Recommended treatment

A.3.3.2.1 Spleen-kidney deficiency with damp turbidity

Treatment principle: Tonify the spleen and kidneys, eliminate dampness, and transform turbidity.

Recommended modified herbs: huangqi, tusizi, dangshen, baizhu, shanyao, huangjixuecao, houpou, wuweizi, danshi, duzhong, sharen, liuyuexue, chenpi, huoxiang, peilan.

A.3.3.2.2 Spleen-kidney deficiency with turbid toxins

Treatment principle: Tonify the spleen and kidneys, transform turbidity, and eliminate any toxins.

Recommended modified herbs: huangqi, tusizi, dangshen, baizhu, shanyao, zhishi, houpou, baihuasheshecao, wuweizi, danshi, huangqin, huanglian, huoxiang, peilan, yinchén, yiyiren, banzhilian.

A.3.3.2.3 Qi-yin deficiency with blood stasis

Treatment principle: Tonify qi, nourish yin, activate blood circulation, and resolve stasis.

Recommended modified herbs: dangshen, maidong, wuweizi, guizhi, taoren, zhigancao, huangqi, shengdi, nüzhenzi, mo hanlian, chuanxiong, danggui, shengdi, honghua, chishao, danshen, mangxiao.

Annex B
(Normative)
Complications related to gastrointestinal lavage with Chinese medicine and management

B.1 Gastrointestinal Mucosal Injury

B.1.1 Clinical Manifestations

Patients experience anal pain, which worsens during defecation, often accompanied by local tenderness. In severe cases, anal bleeding or blood-streaked stool may be observed, and defecation may become difficult.

B.1.2 Management Measures

B.1.2.1 If a patient experiences anal pain, temporarily suspend lavage.

B.1.2.2 For patients with mild pain, advise relaxation and help them divert attention to alleviate pain. For those with severe pain, administer symptomatic treatment immediately. If gastrointestinal bleeding occurs, follow the treatment protocols for gastrointestinal bleeding.

B.2 Gastrointestinal Bleeding

B.2.1 Clinical Manifestations

Patients present with anal bleeding, blood-streaked stool, or blood clots during defecation.

B.2.2 Management Measures

B.2.2.1 When a patient exhibits signs such as rapid pulse, pale complexion, profuse sweating, severe abdominal pain, and restlessness (suggesting severe intestinal spasm or bleeding), immediately cease lavage, and instruct the patient to lie supine.

B.2.2.2 Monitor the patient's vital signs and abdominal conditions. If intestinal perforation or rupture occurs, follow the protocols for intestinal perforation or rupture.

B.2.2.3 Establish intravenous access and administer the appropriate hemostatic medications or local treatment, as per medical guidelines.

B.3 Intestinal Perforation and Rupture

B.3.1 Clinical Manifestations

Patients undergoing lavage may experience sudden abdominal distention and pain. On examination, there may be tenderness or rebound tenderness in the abdomen.

Abdominal ultrasound may reveal abdominal effusion.

B.3.2 Management Measures

B.3.2.1 Immediately cease lavage and place the patient in a supine position. Initiate rescue efforts.

B.3.2.2 Promptly establish intravenous access, optimize preoperative preparation, and conduct surgery as soon as possible.

B.3.2.3 Administer oxygen therapy and cardiac monitoring, and monitor the patient's vital signs.

B.4 Water Intoxication and Electrolyte Imbalance

B.4.1 Clinical Manifestations

B.4.1.1 Patients with water intoxication may initially exhibit restlessness, followed by drowsiness, seizure, or coma. Conjunctival edema may be observed upon examination.

B.4.1.2 Dehydrated patients may complain of thirst. Physical examination may reveal symptoms such as dry skin, tachycardia, decreased blood pressure, reduced urine output, and concentrated urine.

B.4.1.3 Patients with hypokalemia may experience weakness, abdominal distension, decreased bowel sounds or delayed or absent tendon reflexes, and may develop arrhythmias. The electrocardiogram may show ST-T changes and/or U waves.

B.4.2 Treatment Measures

B.4.2.1 In case of water intoxication or electrolyte imbalance, immediately stop the lavage, place the patient in a supine position, and notify the physician for emergency measures.

B.4.2.2 Establish two intravenous pathways and administer Ringer's solution and 4% sodium chloride injection to replenish electrolytes. Use mannitol and furosemide (Lasix) to alleviate cerebral water intoxication.

B.4.2.3 Administer sedatives to alleviate patient seizures.

B.4.2.4 Provide gastrointestinal decompression to relieve abdominal distension.

B.4.2.5 Administer oxygen and conduct electrocardiographic monitoring while observing changes in the patient's vital signs.

B.4.2.6 Monitor urine output and specific gravity. Simultaneously, explain the situation to the patient and comfort their family, maintaining a calm demeanor.

B.5 Collapse

B.5.1 Clinical Presentation

Patients experience sudden nausea, dizziness, and/or pallor. Profuse sweating and even syncope may also occur.

B.5.2 Treatment Measures

Immediately cease lavage, assist the patient to lie supine, keep them warm, and typically, after a brief rest, the symptoms will subside. If the collapse is related to hunger, administer oral glucose water when the patient regains consciousness. If the symptoms persist after a brief rest, provide oxygen, and if necessary, intravenous glucose. Symptoms should gradually improve.

B.6 Gastrointestinal Infection

B.6.1 Clinical Presentation

Abdominal pain, increased frequency of bowel movements, and changes in the volume, color, and/or shape of stools.

B.6.2 Treatment Measures

B.6.2.1 Select appropriate antibiotics based on stool analysis and the pathogenic microorganism's profile.

B.6.2.2 Monitor for any changes in stool volume, color, and characteristics, and record them.

B.6.2.3 Administer antibiotics as per the doctor's instructions.

B.7 Fecal Incontinence

B.7.1 Clinical Presentation

Uncontrolled discharge of feces from the anus.

B.7.2 Treatment Measures

B.7.2.1 For those with fecal incontinence, use rubber (or plastic) sheets and underpads. Clean the anal area and perianal skin with warm water after each bowel movement and keep the skin dry.

B.7.2.2 Whenever necessary, apply ointment around the anal area to protect the skin and prevent infection.

B.8 Perianal Skin Abrasion

B.8.1 Clinical Presentation

Breakdown of the perianal skin, redness, and swelling.

B.8.2 Treatment Measures

B.8.2.1 When the skin is broken, treat it with therapeutic TDP lamp irradiation, twice daily for 15-30 minutes each time.

B.8.2.2 Use aseptic dressing changes according to surgical protocols for wound management.

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