



Counselling customers at risk of the triple whammy effect at community pharmacies – A feasibility study

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ABSTRACT

The combination of diuretics, angiotensin-converting enzyme inhibitors (ACE-i)/angiotensin II receptor blockers (ARBs) and non-steroidal anti-inflammatory drugs (NSAID) involves a risk of acute renal failure known as the triple whammy effect (TWE). NSAID can be provided by prescription or over the counter (OTC) and community pharmacies counsel on this medication every day to contribute to medication safety. The objective of this study is to test the feasibility of an intervention where community pharmacies identify and counsel customers at risk of the TWE.

Participating pharmacies were recruited across Denmark and the Faroe Islands. In April to May 2021, all staff at 13 community pharmacies chose 10 workdays to collect data in an electronic tool on their risk assessment, the customers' medication, and counselling about the TWE for customers asking for NSAID. Pharmacy staff were instructed in correct data collection and received learning material and a patient information leaflet on the TWE. These data were analysed descriptively. Staff evaluated the learning material and patient information leaflet in a questionnaire. The quantitative answers from the questionnaire were analysed descriptively and the qualitative answers were analysed using content analysis.

According to the pharmacies' risk assessment, 12.1% ($n = 215$) of customers asking for NSAID were at risk of the TWE. The data on customers' medication showed that only 8.0% ($n = 142$) were actually at risk of TWE. Of those, 43.0% ($n = 61$) asked for NSAID on prescription and 57.0% ($n = 81$) for OTC. In the evaluation of materials pharmacy staff reported overall satisfaction with the learning material, which they reported increased their knowledge of TWE and helped them in their counselling. They also reported satisfaction with the patient information leaflet.

Despite pharmacy staff reporting satisfaction with the learning material, it still did not educate staff well enough in assessing the risk of TWE for customers asking for NSAID. More research is needed on TWE interventions in community pharmacies because this study shows that there is a potential for community pharmacies to identify and counsel persons at risk of the TWE.

1. Introduction

It is well-documented that combining diuretics with angiotensin-converting enzyme inhibitors (ACE-i) or angiotensin II receptor blockers (ARBs) and non-steroidal anti-inflammatory drugs (NSAID) involves a risk of acute renal failure.^{1,2} This combination is known as triple whammy. The combination causes a 31% increased risk of acute renal failure, which increases within the first 30 days of treatment with

NSAID.¹ In total, the three groups of medicine, used either individually or in combination, comprise more than half of the reported instances of drug-induced acute renal failure. Especially older people are at risk of drug-induced acute renal failure, as renal function decreases with age.³ Some studies have investigated the prevalence of the combination of prescribed NSAID, ACE-i/ARBs and diuretics and found that 0.3% of patients ($N = 246,721$, $n = 730$)² and 1.4% ($N = 2007$, $n = 28$)⁴ received prescriptions on medication combination increasing the risk of triple

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whammy effect (TWE).

A study explored views and practices of general practitioners (GPs) and community pharmacists regarding patient education about the risk of acute kidney injury (AKI) because of medication combinations, e.g., the triple whammy combination. The results from two surveys for GPs and community pharmacists working in Hawke's Bay, New Zealand, showed that both GPs and community pharmacists were confident in providing patient education on discontinuing risk medication to reduce the risk of AKI. GPs had confidence in pharmacists providing this education and pharmacists were willing to do it if additional training, prescriber support and remuneration was provided. Over half of the GPs wanted pharmacists to contact them regarding triple whammy prescriptions. However, community pharmacists did not routinely provide patient education or contact GPs, and the study concluded that collaborative planning between health care professionals would be beneficial to clarify professional roles and develop consistent patient education.⁵

Another project from New Zealand tested an intervention to identify and help patients at risk of the TWE who asked for NSAID on prescription. The intervention involved repeated interdisciplinary meetings with knowledge sharing and discussions between physicians, nurses, and community pharmacists. It also involved medication reviews carried out by GPs, information material for patients and health professionals on the TWE, and strengthened focus in the pharmacies' counselling on patients' risk of triple whammy. It showed that health professionals became increasingly aware of the risk of triple whammy, and during the five years of work, the combination of the three medications – diuretics, ACE-i/ARBs and NSAID – was prescribed for fewer patients than before the intervention.⁶

Many studies have shown that community pharmacy staff, both pharmacists and pharmacy technicians (in Denmark technicians are the largest employee group at community pharmacies), can identify drug-related problems (DRPs) and counsel patients on both prescription and over-the-counter (OTC) medication.^{7–14} In Denmark NSAID is provided by community pharmacies on prescription and as OTC medication. Ibuprofen 200 mg and acetylsalicylic acid up to 500 mg are provided as OTC medication in Denmark. A Finnish study showed that community pharmacists identify, counsel and prevent DRPs related to OTC medications, with 26.3% of the 339 identified DRPs problems concerning high-risk medications and the most frequent one being NSAID.¹⁴ A Danish mapping of community pharmacy technicians' counselling showed that they identified DRPs for 15.8% of 2800 patients requesting prescription medication, OTC medication and non-medical products. Their counselling solved, or partially solved, problems for 70.4% of these patients.¹³

The objective of this study was to test the feasibility of an intervention where staff at community pharmacies identify and counsel pharmacy customers on the risk of the TWE, including both OTC and prescription NSAID.

2. Material and methods

2.1. Participants

One hundred and five community pharmacies, which at the time were members of the Danish Network for Community Pharmacy Practice Research and Development (NUAP),¹⁵ were invited to participate in the study by email and in the Facebook group of NUAP from December 2019 to February 2020 and again in January–March 2021. Because of the COVID-19 pandemic the study was paused, and pharmacies were recruited in two periods. The pharmacies were located across Denmark and the Faroe Islands, representing both rural and urban areas. Thirteen community pharmacies, including their branches (in total, 24 pharmacy units), wanted to participate in the study and were all included in the study.

2.2. Data collection and analysis of customers asking for NSAID, assessment of triple whammy risk and counselling

An electronic data collection tool was developed to collect data on the community pharmacies' risk assessment, customers' medication and counselling for customers asking for prescription or OTC NSAID. The tool was developed through discussion in the project group that consisted of three community pharmacists and two researchers. The tool was pilot tested for a week at a community pharmacy for 10 customers and adjusted into the final tool.

The 12-item tool explored information on whether customers requested prescription or OTC NSAID, were first-time users of NSAID, were at risk of triple whammy, their use of ACE-i/ARBs, diuretics and NSAID, their wish for counselling and the outcome of the counselling. An English version is provided in Appendix A. REDCap, a secure web platform for building and managing online databases and surveys,¹⁶ was used to configure the tool and store data.

The participating community pharmacy staff selected 10 workdays in the period April–May 2021 where they included and collected data for all pharmacy customers who asked for NSAID either OTC or on prescription for themselves. They collected the data in the electronic data collection tool in REDCap. Data on customers asking for NSAID was analysed using descriptive statistics in Microsoft Excel.

2.3. Introduction to the participating community pharmacies and materials

Prior to the data collection, all participating employees at the pharmacies needed to go through a PowerPoint presentation describing the data collection to ensure that they were able to collect data correctly. Furthermore, the responsible person at each pharmacy was provided with learning material with facts on the TWE and the risk of acute kidney injury when patients receive ACE-i/ARBs, diuretics and NSAID at the same time. The responsible person presented the learning material to all participants at the pharmacy to enhance their competences in identifying customers at risk of triple whammy and how to counsel them. The pharmacies were also provided with a patient information leaflet with facts on the TWE, advice on talking to a physician and a list of ACE-i, ARBs, diuretics and NSAID to be used in the counselling of patients at risk of triple whammy. The learning material and patient information leaflet were developed by the three community pharmacists in the project group and pilot tested at one pharmacy before testing at a larger scale.

2.4. Evaluation of learning materials and patient information leaflet

In June 2021, after completing the data collection on customers asking for NSAID, participating pharmacy staff evaluated the learning material and the patient information leaflet on the TWE through an electronic questionnaire in Microsoft Forms. See the full questionnaire in Appendix B. The questionnaire consisted of quantitative questions using a scale from 0 to 10 (where 10 is the best), with a possibility to clarify their answers with free text. Free text answers were analysed through content analysis, with two members of the project group performing four steps: decontextualization, recontextualization, categorisation and compilation.¹⁷

2.5. Ethics

According to Danish legislation and the EU General Data Protection Regulation ACT (GDPR), participating customers could not be identified from the data collection. The names of the pharmacies are only known by the authors. Consequently, according to Danish legislation, no approval was required in terms of either ethics or data protection.

3. Results

3.1. Community pharmacies' assessment of risk and counselling

The participating pharmacies assessed and collected information about 1779 customers who asked for OTC or prescription NSAID for themselves. 215 customers (12.1%) were, according to the pharmacies' assessment, at risk of the TWE, 1557 (87.5%) were not at risk and, for seven customers, (0.4%) the pharmacies did not cover the risk. Looking at the data of the 1779 customers' medication (ACE-i/ARBs and diuretics), only 142 (8.0%) had the combination of ACE-i/ARBs, diuretics and NSAID that places them at actual risk of the TWE. The results for the 142 customers at risk are presented in Fig. 1.

For the 142 (8.0%) at risk of the TWE, 61 (43.0%) asked for NSAID on prescription and 81 (57.0%) asked for NSAID OTC. Seven of the 142 customers (4.9%) at risk were first-time users of NSAID, whereas 131 (92.3%) had used NSAID multiple times, and 4 (2.8%) were not asked. Most of the customers received counselling ($n = 139$, 97.9%) and only three did not, because they were busy or not interested. Of the 139 customers who wanted counselling, 26 (18.7%) did not buy NSAID after counselling, whereas 6 were on prescription, while 113 (81.3%) bought NSAID, whereas 52 were on prescription. Of the 26 customers who did not buy NSAID, 15 (57.7%) bought paracetamol instead. Of the 142 customers at risk of triple whammy, 103 (72.5%) were referred to a physician and 39 (27.5%) were not.

3.2. Evaluation of learning material and patient information leaflet

Responses to the questionnaire evaluating the learning material and patient leaflet were received from 79 staff members from all 13 participating pharmacies, with between two and 11 answers per pharmacy. Of the 79 answers, 39 were from pharmacy technicians, 10 from pharmacy technician students, 19 from pharmacists, four from pharmacist students and seven from pharmacy owners.

Regarding the two questions about the extent to which the teaching material has helped staff increase their knowledge of triple whammy and helped them in counselling, the median for both questions was 8 both for all staff gathered and for pharmacy technicians and pharmacists (Table 1).

The learning material have been used at all community pharmacies. The pharmacy staff assessed that the learning material provided useful knowledge for them to give customers better counselling on the triple

Table 1

Pharmacy staff's evaluation and assessment of the learning material on the triple whammy effect.

	Increased knowledge – median (IQR)	Helped in counselling – median (IQR)
Learning material for pharmacy staff gathered (79)	8 (3)	8 (3)
Learning material for pharmacy technicians (also students) (49)	8 (3)	8 (3)
Learning material for pharmacists (also students and pharmacy owners) (30)	8 (2)	8 (2.5)

whammy risk. They were satisfied with the explanations, illustrations, and in-depth background. Some thought the level was appropriate, others had added their own slides with more information on the TWE and possible acute kidney injury, as they felt details were missing. The participants described that they had different competencies on the subject; some did not gain new knowledge, some supplemented their existing knowledge, and some gained all new knowledge.

The participants pointed out that the benefit of the teaching material depended on the teachers' knowledge of the TWE and the competence to teach and on whether time was prioritised for teaching.

Regarding the two questions about the extent to which the patient information leaflet has helped staff in counselling and whether it has improved counselling for customers, the rate on both questions was 8 both for all staff gathered and for pharmacy technicians and pharmacists except the question on how the leaflet has helped staff in counselling the median was 7 for pharmacy technicians (Table 2).

The pharmacy staff reported that the leaflet contributed to improving their counselling. They assessed that the content provided a good overview and was easy to understand. The medicine list of the three drug groups was especially useful. The leaflet was used to start a dialogue and having something in writing made it easier for the pharmacy staff to provide counselling. Some staff did not use the leaflet because they assessed that their customers did not need written information after receiving verbal counselling.

The staff experienced that customers appreciated the opportunity to take home the leaflet to read and bring it to their GP. Customers have also become aware of the TWE and how to avoid it. Some staff experienced that customers were overwhelmed by the amount of information and that the leaflet may seem frightening, for example due to use of the

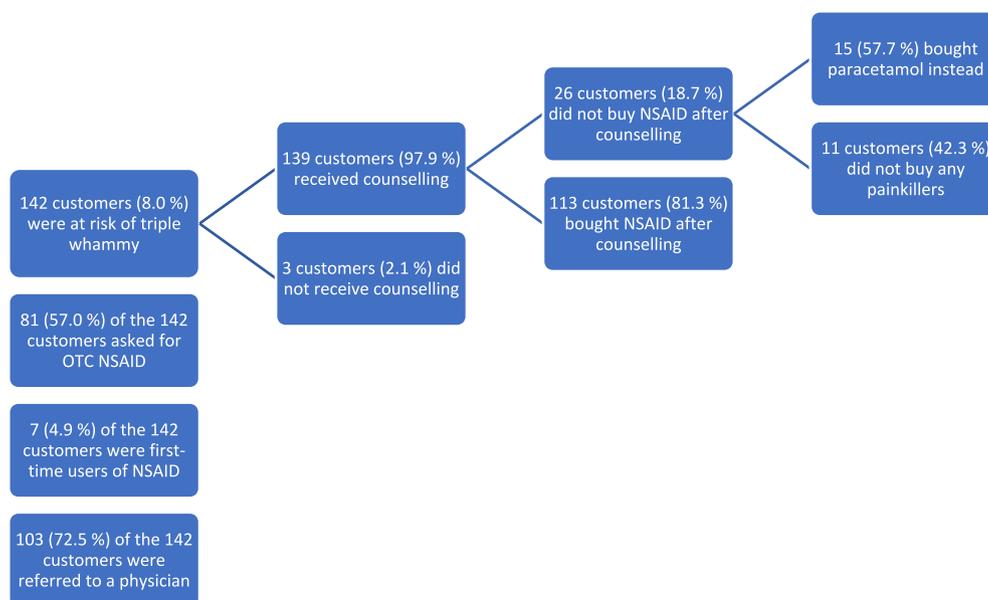


Fig. 1. Results for the 142 customers at actual risk of the triple whammy effect.

Table 2

Pharmacy staff's evaluation and assessment of the patient information leaflet on the triple whammy effect.

	Helped in counselling – median (IQR)	Better counselling – median (IQR)
Patient information leaflet, staff gathered (79)	8 (4)	8 (4)
Patient information leaflet, pharmacy technicians (also students) (49)	7 (5)	8 (5)
Patient information leaflet, pharmacists (also students and pharmacy owners) (30)	8 (4.75)	8 (3.75)

words “dangerous trio”.

4. Discussion

In this study staff at community pharmacies assessed that during a period of 10 days, 12.1% of customers asking for NSAID were at risk of TWE. When calculating the actual risk from the customers' medication the number is 8.0% where 57.0% of customers asked for OTC NSAID and 72.5% were referred to a physician. Studies from Japan and Germany found a lower percentage of persons at risk of the TWE – 0.3%² and 1.4%⁴ respectively – but those numbers are based on prescribed NSAID, whereas this study included both prescribed and OTC NSAID. Especially the OTC NSAID customers are important to identify at the pharmacy because they can only be identified here. Also, some types of NSAID (e. g., ibuprofen and acetylsalicylic acid) are available in retail shops in several countries, including Denmark, where no counselling is provided, and the customer only has access to the information leaflet in the medication package. Through a qualitative textual analysis of Danish information leaflets for non-pharmacy restricted OTC medicines, a study has investigated the extent to which information leaflets comply with current legislation and guidelines as far as lay-friendliness is concerned. The study found that the leaflets are far too complex to stand alone as a source of information for patients using the medication.¹⁸ So, the community pharmacies play an important role in counselling about medication and prevention of inappropriate use of especially OTC medication where counselling from another professional is lacking. This feasibility study shows that it is possible for community pharmacy staff to identify customers at risk of the TWE when asking for OTC NSAID and potentially prevent adverse events by counselling and referring the customers to a physician. For prescription NSAID, the pharmacies' role is to counsel about safe use and the risk of triple whammy and to refer customers to a physician when needed.

In this feasibility study the percentage of customers who buy NSAID after counselling is higher (81.3%) than those who refrain from buying it after counselling (18.7%) despite the counselling about the risk of TWE from community pharmacy staff. Even if customers buy the NSAID, it is not known whether they take it and whether they follow the advice from community pharmacy staff when they have thought about it or talked to their physician. It is also possible that a physician has already assessed the treatment when customers ask for prescription NSAID. In that case, a patient information leaflet like the one in this study could be a complementary tool to the verbal counselling at the pharmacy to help the customers decide whether they will continue to take the NSAID or discuss it with their physician. The pharmacy staff evaluated that the leaflet was a good dialogue tool in the counselling and that customers appreciated the opportunity to read the leaflet. A limitation in this study is that the patient experience of the leaflet and counselling has not been evaluated, so the patient perspective on a wish for patient-centred counselling is lacking.

The purpose of the learning material was to educate pharmacy staff to assess the risk of the TWE for pharmacy customers asking for NSAID. The material was presented at a teaching session by the responsible

person at the pharmacy to all participating employees at the pharmacy. The results showed that 4.1% of the pharmacy customers (a difference from 12.1% to 8.0%) assessed by the staff to be at risk of triple whammy were not actually at risk. This difference in number of customers in risk could be because of wrong or missing data registrations on the customers' medication despite the fact that all pharmacy staff were introduced in how to register data correctly. It could also be because of different educational levels for pharmacy technicians and pharmacists despite Danish pharmacy technicians have a three-year academy profession degree equal to a Bachelor of Pharmacy. They are also the biggest working group in Danish community pharmacies and therefore also in this study (49). Another thing which more likely could affect the 4.1% difference is the level of the learning material and the quality of the teaching on TWE at the community pharmacies. All responsible persons at the pharmacies were pharmacists and the evaluation of the learning material shows that the quality of the teaching depends on the knowledge and teaching competences of the teacher at each pharmacy, which maybe together with a not appropriate level of the learning material may result in different levels of education on the TWE at the 13 participating pharmacies. This was not measured or followed up by the project group which is a limitation in the study. The staff's evaluation of the learning material did not vary regardless of whether they were pharmacists or pharmacy technicians.

Another limitation is that the study has not provided a drop-out analysis. It has not been possible to check whether the pharmacies collected data on all NSAID customers who picked up NSAID in the required 10 days. To overcome this limitation, the data collection tool contained a question where the staff could indicate that they had forgotten to ask and assess whether a customer was at risk of triple whammy, but this depended on the pharmacy staff actually ticking the box. Because of the limitation, the number of customers at risk of the TWE cannot be used as an actual mapping of customers at risk. The study focused on the feasibility of an intervention where community pharmacies identify and counsel pharmacy customers at risk of the TWE with the support of learning material and a patient information leaflet.

5. Conclusions

This feasibility study shows that despite pharmacy staff reporting satisfaction with the learning material, the staff were not educated well enough in assessing on the risk of triple whammy for customers asking for NSAID through the teaching material. The pharmacy staff assessed that more customers were at risk than was actually the case. 12.1% ($n = 215$) of all customers asking for NSAID were at risk of the TWE according to the pharmacy staff assessments, while the number was 8.0% ($n = 142$) based on the medications of the customers. More research is needed on how to carry out TWE interventions in community pharmacies so they can identify and counsel customers who need it, especially with focus on how to educate community pharmacy staff on the TWE – because this study shows that there is a potential to prevent acute renal failure by identifying persons at risk of triple whammy when they ask for NSAID at community pharmacies.

Formatting of funding sources

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The Education and Development Fund contributes to professional training, development and improvement of the working conditions for community pharmacists in Denmark. The fund has supported this research by funding the layout and printing of the patient information leaflets used in the study. It has also supported the publication fee.

Declaration of Competing Interest

None.

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Appendices

A) Data collection tool for data on customers at risk of triple whammy

The triple whammy effect

Please reply to the questionnaire below about your assessment and counselling with NSAID drugs
Thank you.

Which pharmacy are you employed at?

Registration

- For registration
 Forgotten to register
-

Did the customer buy NSAID on prescription or over the counter?

- On prescription
 Over the counter
-

Is the customer interested in receiving counselling?

- Yes
 No
-

Is the customer a first-time user of NSAID?

- Yes. The customer is using NSAID for the first time
 No. The customer has used NSAID before
 Forgot to ask the customer
-

Is the customer at risk of the triple whammy effect?

When buying NSAID, customers should be actively asked whether they use:

- Blood pressure medications of the type ACE-inhibitors or Angiotensin-II-receptor blockers
- Diuretics

- Yes
 No
 Forgot to ask the customer
-

Which of the following drugs is the customer using?

- ACE-inhibitor
 Angiotensin-II-receptor blockers
 Diuretics
-

Did you provide verbal counselling on the triple whammy effect

- Yes
 No
-

If no, why not?

Did the customer receive a patient information leaflet on the triple whammy effect? Yes
 No

If no, why not?

Did the customer buy NSAID after your counselling? Yes
 No

Did the customer buy any painkillers other than NSAID? Yes, the customer bought paracetamol (e.g., Panodil®, Pamol®, Pinex®)
 Yes, the customer bought something else
 No, the customer did not buy any other painkillers

Other things

Was the customer referred to a physician? Yes
 No

B) Questionnaire for pharmacy staff for evaluation of learning material and patient information leaflet

Evaluation of materials on the triple whammy effect

*Required

1. Which pharmacy are you employed at? *
2. What is your job function? *
 - Pharmacy technician
 - Pharmacy technician student
 - Pharmacist
 - Pharmacist student
 - Pharmacy owner
 - Project manager (pharmacist)
3. How many employes have joined the project at the pharmacy in total? (Should not be divided into occupational groups or function) *
4. What is the total number of employees at the pharmacy? (Should not be divided into occupational groups or function) *
5. Have you used the learning material on the triple whammy effect at your pharmacy? *
 - Yes
 - No
6. Please elaborate on the above question

The learning material on the triple whammy effect

7. How did you learn about the triple whammy effect? (You may select several boxes) *
 - Presentation of the learning material by project manager
 - Reading the learning material
 - Reading of the patient information leaflet
 - Knowledge from my own search
 - Knowledge from an earlier project
 - Knowledge from a course
 - Knowledge from The Danish Network for Community Pharmacy Practice Research and Development
 - I do not know about the triple whammy effect
 - Other
8. On a scale of 0 to 10, 10 being the highest, how much has the learning material helped you improve your knowledge on the triple whammy effect? (Skip the question if you are not familiar with the learning)

0	1	2	3	4	5	6	7	8	9	10
To a very low extent					To a very high extent					

9. Please elaborate on the above question

10. On a scale of 0 to 10, 10 being the highest, how much has the learning material helped you in your counselling of customers with the combination of the three drugs? (Skip the question if you are not familiar with the learning material)

0	1	2	3	4	5	6	7	8	9	10
To a very low extent					To a very high extent					

11. Please elaborate on the above question

12. What are your suggestions for improvements of the learning material?

The patient information leaflet on the triple whammy effect

13. On a scale of 0 to 10, 10 being the highest, how much has the patient information leaflet on the triple whammy effect helped you in your counselling of customers with the combination of the three drugs? *

0	1	2	3	4	5	6	7	8	9	10
To a very low extent					To a very high extent					

14. Please elaborate on the above question

15. On a scale of 0 to 10, 10 being the highest, how much has the patient information leaflet on the triple whammy effect improved the counselling of customers with the combination of the three drugs? *

0	1	2	3	4	5	6	7	8	9	10
To a very low extent					To a very high extent					

16. Please elaborate on the above question

17. What are your suggestions for improvements of the patient information leaflet?

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