Le Infezioni in Medicina, n. 4, 518-524, 2024
doi: 10.53854/liim-3204-10

Single dose ivermectin for scabies pre-emptive therapy among healthcare workers in Careggi University Hospital, Florence, Italy

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Article received 15 July 2024 and accepted 14 October 2024

SUMMARY

Introduction: Scabies is a neglected disease that cause outbreaks in facilities such as hospitals and prisons. In Europe, treatment with 2 doses of ivermectin 200 mcg/kg, 7 days apart, is authorised and recommended especially in population mass treatment. We describe the management of a mass pre-emptive therapy of primary contacts of a confirmed case of classic scabies among health care workers.
Patients and Methods: Hospital personnel were evaluated, and at-risk contacts were treated with oral ivermectin 200 mcg/kg single dose if asymptomatic. Hospital staff were called after 7, 30, and 60 days after the first visit to assess presence of adverse drug reactions (ADRs) or symptoms compatible with scabies.
Results: Among 27 patients evaluated, 19/27 (70.4%) received single dose ivermectin for scabies pre-emptive therapy. A total of 11/13 patients were nurses, and 8/14 were healthcare assistants. A total of 87 tablets of ivermectin were administered, with a total cost of 423.69 euros. Two people reported ADRs at 7 days; one and two patients reported possible ADRs at 30 and 60 days, respectively. The efficacy in preventing scabies was 100%.
Discussion and conclusions: To our knowledge, this is the first Italian experience in which a single dose of ivermectin has been implemented for mass pre-emptive therapy in asymptomatic primary contacts of classical scabies, showing excellent efficacy of the drug even when used as a single dose.

Keywords: scabies, pre-emptive treatment, ivermectin, in-hospital outbreak.

INTRODUCTION

Scabies is an ectoparasitic disease caused by *Sarcoptes scabiei* varietas *hominis*, endemic in low and middle-income countries and commonly cause of outbreaks in facilities such as hospitals, nursing homes and prisons [1, 2]. The disease was recognised by World Health Organisation (WHO)

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as a neglected disease since 2017 and as the 101st disease for age-standardised global DALYs in the Global Burden of Disease 2015 study [3, 4]. Scabies leads to important stigma and occasionally to dangerous complications determined by bacterial skin infections [2, 5].

Primary infestation incubation period is two to eight weeks, although the range is highly variable mostly because of diagnostic delay [1, 6-8]. Scabies transmission mainly occurs by intense skin-to-skin contact, especially during sexual contact, and is most common in single men, men who have sex with men and people with sporadic sexual contacts. Transmission through indirect contacts is rare, and it is especially important in crusted scabies [5, 9, 10]. Outbreaks of the disease are common in institutions and enclosed communities, particularly where crowding occurs [2].

According to 2017 European Guidelines for the management of scabies, treatment of choice is 5% permethrin cream 30 g applied topically twice, 7-14 days apart. Ivermectin 200 mcg/kg 2-dose (7 days apart) is also recommended and approved for classical scabies treatment in several European countries and Australia, while is not currently validated by Food and Drugs Administration [7, 9, 11]. The two-week regimens with ivermectin or topical permethrin have similar efficacy (68% *vs* 74%, respectively) [11]. Permethrin acts faster, leading to parasite clearance within one week; moreover, the drug is both acaricidal and ovicidal [12]. The repetition of the treatment with permethrin after 7-14 days is usually recommended mostly because of inadequate administration during the first application [5]. Ivermectin acts slower than permethrin, but parasite clearance is comparable at 2 weeks after the treatment, both with one and two doses [11, 12]. Since the drug is only acaricidal (with limited ovicidal activity), a double dose is generally preferable, although in some countries it can be decided according to physician judgement [13-16].

Additionally, ivermectin is recommended in case of mass population to all at-risk population irrespective of symptoms [9]. A single dose of 200 mcg/kg is considered effective: the necessity of the second dose administration, although recommended, still need to be assessed [9, 17].

We describe the outcome and adverse drugs reactions (ADRs) of pre-emptive therapy with ivermectin single dose among health care workers (HCWs) who were primary contacts of a patient admitted to internal medicine ward in Careggi University Hospital (Florence, Italy) and diagnosed with classic scabies.

PATIENTS AND METHODS

Index case

The index case was a 93-year-old man admitted on February 11th, 2023, to internal medicine ward in Careggi University Hospital (Florence, Italy) for respiratory insufficiency, congestive heart failure, and SARS-CoV-2 infection (positive antigenic nasal swab). He was isolated with COVID-19 precautions according to hospital procedures (FFP-2 mask, double set of gloves, single-use lab coat, eyeshade): precautions for contact and airborne transmitted infections were removed on February 26th after a negative SARS-CoV-2 antigen nasal swab. On February 28th he was clinically diagnosed with classic scabies according to 2020 IACS criteria [2]; patient reported itching for 7 days before hospital admittance, and diagnosis was confirmed by both dermatology and infectious disease specialists. The patient was successfully treated with oral ivermectin (200 mcg/kg) and topical application of 5% permethrin cream at the moment of diagnosis and 7 days later.

Management

After scabies diagnosis, demographic data of hospital staff who had contact with the patient during his hospitalisation were collected, and they were asked to perform a medical visit to assess need for scabies pre-emptive therapy and/or treatment. Name, surname, occupation, telephone number, kind of contact and weight (in case of defined at-risk contact) were collected during the visit.

At-risk personnel were considered if primary contact (direct contact with the index case) was performed without precautions for contact transmitted infectious diseases (i.e. gloves and single-use lab coat) *or* was superior to 15 minutes along with procedures causing intense skin-to-skin exposure (e.g. washing the patient, changing bed laundry, etc.). Health care workers evaluated were nurses and healthcare assistants (HAs); medical doctors and cleaning personnel were excluded since medical visits and room cleaning were not considered at-risk procedures for transmission according to the literature [5].

In cases of asymptomatic at-risk contact, a single dose of oral ivermectin 200 mcg/kg (assumed with meals) was prescribed, while in cases of lesions or symptoms suspicious for scabies the same dosage was repeated 7 days after the first dose. The number of tablets (tbls) (ivermectin 3 mg) was decided according to patient weight and package leaflet (36-50 kg: 3 tbls; 51-65 kg: 4 tbls; 66-79 kg: 5 tbls; ≥ 80 kg: 6 tbls) [16].
Hospital personnel who have taken ivermectin was called at 7, 30, and 60 days from the visit to assess the presence of ADRs (cardiovascular, central nervous system (CNS), gastrointestinal and dermatological) and symptoms or signs suspicious for scabies, in line with the highest incubation period described (i.e. eight weeks) [5, 7]. Untreated staff were called 60 days after the visit to confirm the absence of scabies symptoms and signs.

Intervention costs
Costs were calculated according to hospital pharmacy. In the public system of Tuscany region, a package of thirty grams of 5% permethrin cream costs 7.25 euros (retail price: 23.6 euros). Eight tablet package of 3 mg ivermectin costs 38.94 euros (retail price: 60.0 euros), 4.87 euros for each tablet.

Statistical analysis
Descriptive analysis was employed to illustrate population characteristics. Categorical variables were evaluated with X2/Fisher's exact test, and continuous variables were evaluated with the Mann–Whitney test. STATA v13.0 (STATACorp, USA) was used for statistical analyses.

RESULTS

Twenty-seven out of 30 (90.0%) HCWs presented to the infectious disease outpatient clinic for scabies pre-emptive therapy/treatment evaluation. General characteristics, contact type and management strategies are reported in Table 1. The overall population median age was 39 years (IQR 26-56), with the nurse group being younger than the HA group (27.0 *vs* 46.5 years old). Only one nurse reported immunosuppressive status (she was assuming adalimumab, an anti-TNF alpha agent, for Crohn's disease), and 6 persons (3 nurses and 3 HAs) reported history of allergy (seasonal allergy or atopic dermatitis).
Eleven out of 13 nurses and 8/14 HAs (86.4% *vs* 57.1%) were considered at-risk personnel. Overall, 19/27 (70.4%) persons received pre-emptive ther-

Table 1 - General characteristic, type of contact and management (observation, pre-emptive therapy or treatment) of internal medicine ward health care workers who were primary contacts with a case of classical scabies, divided in healthcare assistants and nurses.

	HA (n=14)	*Nurses (n=13)*	*p-value*
Female (n, %)	12 (85.7)	10 (76.9)	0.557
Age (median [IQR])	46.5 [36-52]	27 [26-56]	0.215
Weight (median [IQR])[1]	69 [54-73]	61 [59-78]	0.877
Immunosuppression (n, %)	0 (0.0)	1 (7.69)	0.290
Allergies (n, %)	3 (21.4)	3 (23.8)	0.918
Symptoms (n, %)	0 (0.0)	1 (7.69)	0.290
Lesions (n, %)	0 (0.0)	1 (7.69)	0.290
Contact			
Protected (n, %)	6 (42.9)	2 (15.4)	0.295
Strict/Prolonged (n, %)	5 (35.7)	7 (53.9)	
Not protected (n, %)	3 (21.4)	4 (30.8)	
Management			
Observation (n, %)	6 (42.9)	1 (7.7)	0.081
Prophylaxis (n, %)	8 (57.1)	11 (84.6)	
Treatment (n, %)	0 (0.0)	1 (7.69)	

[1]Weight was reported only for the personnel who were prescribed ivermectin. HA: health care assistants; IQR: interquantile range.

apy with a single dose of ivermectin (11 nurses and 8 HAs).
Ivermectin pre-emptive therapy was significantly more prescribed to the nurse population (91.7% *vs* 57.1%, p=0.048), with a total of 49 and 38 tablets prescribed to the nurse and HA group, respectively (Table 2). Considering the cost of 4.87 euros per tablet (3 mg ivermectin), the overall cost was 423.69 euros (total of 87 tbls). Management with 5% permethrin cream, costing 7.25 euros per package (30 g), would bring the total cost to 137.75 euros.
At the seven-day follow-up call, 19 out of 19 treat-

Table 2 - Prescribed ivermectin among evaluated personnel, pill burden and costs, adverse drug reactions and incidence of scabies during a 60 days phone monitoring, divided by healthcare assistants and nurses.

	HA (n=14)	*Nurses (n=13)*	*p-value*
Pre-emptive therapy administered (n, %)	8 (57.1)	11 (91.67)	*0.048*
Total number of ivermectin 3 mg tablets (n)	38	49	*0.049*
Total cost of the intervention (euro)[1]	185.06	238.63	–
Total cost with hypothetical permethrin treatment (euro)[2]	58.00	79.75	–
7-days follow up, Adverse events			
Total number of phone answers (n, %)	8 (100.0)	11 (100.0)	–
Overall reported adverse event (n, %)	2 (25.0)	0 (0.0)	0.080
CNS (n, %)	0 (0.0)	0 (0.0)	–
CV (n, %)	0 (0.0)	0 (0.0)	–
Dermatological (n, %)	1 (12.5)	0 (0.0)	0.228
GI (n, %)	1 (12.5)	0 (0.0)	0.228
30-days follow up, Adverse events			
Total number of phone answers (n, %)	6 (75.0)	9 (81.8)	0.719
Overall reported adverse event (n, %)	0 (0.0)	1 (11.1)	0.398
CNS (n, %)	0 (0.0)	1 (11.1)	0.398
CV (n, %)	0 (0.0)	0 (0.0)	–
Dermatological (n, %)	0 (0.0)	0 (0.0)	–
GI (n, %)	0 (0.0)	0 (0.0)	–
60-days follow up, Adverse events			
Total number of phone answers (n, %)	8 (100.0)	11 (100.0)	–
Overall reported adverse event (n, %)	1 (12.5)	1 (9.09)	0.811
CNS (n, %)	0 (0.0)	1 (9.09)	0.381
CV (n, %)	0 (0.0)	0 (0.0)	–
Dermatological (n, %)	1 (12.5)	0 (0.0)	0.228
GI (n, %)	0 (0.0)	0 (0.0)	–
Incidence of scabies[3]			
7-days follow-up (n,%)	0 (0.0)	0 (0.0)	–
30-days follow-up (n,%)	0 (0.0)	0 (0.0)	–
60-days follow-up (n,%)	0 (0.0)	0 (0.0)	–

[1]Cost was calculated as 4.87 euros per tablet.
[2]Cost was calculated as 7.25 euros per package.
[3]Seven and thirty days follow-up was assessed only for personnel administered with ivermectin, sixty days follow-up was assessed for all evaluated personnel.
CNS: central nervous system; CV: cardiovascular; GI: gastrointestinal; HA: health care assistants. Italic character in *p*–value column was used for statistically significant results.

ed personnel answered: one HA reported nausea after 1 day from the ivermectin assumption, resolved without any medication; another HA reported general itching without lesions suspicious for scabies. Overall, 2/6 (25.0%) of HAs referred ADRs, while no one in the nurse group referred any reaction (25.0 *vs* 0.0%).
At the 30-day follow-up call, only 16/19 (84.2%) of the treated staff answered. Of them, only one nurse reported episodes of dizziness, nausea, vomiting and headache, started 15 days after the administration of 6 tablets of 3 mg ivermectin.
At the 60-day follow-up call, 27/27 of the evaluated staff answered. Scabies was not detected in either the treated or untreated cohort. One HA reported itching in the breast, elbow and proximal thumb areas approximately 45 days after treatment, already vanished at the moment of the phone call: the patient was visited and no lesions compatible with scabies were evidenced. The same nurse who reported the CNS symptoms at the 30-day follow-up call reported a slight improvement of the clinical picture, not yet resolved.

DISCUSSION

We described the management of a mass pre-emptive therapy in primary contacts of a confirmed case of classic scabies among HCWs. Several approaches to scabies outbreaks have been described in the literature. In some experiences, primary contacts were monitored, and treatment was started only after symptoms appearance [18-20]; however, most guidelines (European, CDC, United Kingdom) recommend to administer pre-emptive therapy to all primary contacts, regardless of symptoms [7, 9, 21, 22]. There is no current consensus addressing the right posology of ivermectin in cases of pre-emptive therapy (scabies exposure without clinical lesions or symptoms compatible with scabies). Different studies concerning scabies outbreaks in prisons, nurse facilities or hospitals often described the use of multiple doses of ivermectin, mostly in patients already showing signs of scabies [1, 18, 19, 21, 23]. European guidelines support the administration of two doses of ivermectin to all at-risk population, although the importance of the second dose still need to be assessed [9].
In this experience, oral ivermectin was employed to simplify the administration of scabies pre-emptive therapy. Ivermectin was administered only once in case of absence of symptoms or signs consistent with scabies in contrast to the majority of published experiences: since the visit was carried out three to five days after removal of precautions for contact transmitted infectious diseases, we considered time elapsed since contact not enough for female *Sarcoptes* to lay eggs. This treatment posology was combined with a strict follow-up to ensure the absence of scabies for up to 8 weeks after the visit. Efficacy in preventing scabies was 100% and was evaluated at 7, 30, and 60 days after drug administration for all treated contacts; untreated group did not show any signs or symptoms compatible with scabies after 60 days. This case is not identifiable as an outbreak (defined traditionally as two or more consecutive cases within 4-8 weeks [7]).
In a recent meta-analysis, ivermectin-related ADRs were slightly higher compared to topical permethrin after 4 weeks from the treatment beginning (5% *vs* 4%), although no withdrawal was reported [11]. Ivermectin ADRs commonly reported in the literature include worsening itching, headache, dizziness, hypotension, nausea, and vomiting [12, 24-26]: some of these adverse events are believed to result from the death of the parasites rather than from a reaction to the drug [27]. In our experience, one patient reported gastrointestinal symptoms, and one patient reported itching shortly after the ivermectin assumption. A female HA, with positive medical history for seasonal allergy, reported symptoms 45 days after the treatment. Symptoms were already self-resolved during the phone call and no lesions compatible with scabies were detected at the visit: the episode could be compatible with a seasonal allergic reaction, and no blood test was requested since pruritus was already vanished [28].
A 36-year-old female patient reported vomiting, nausea, and dizziness two weeks after the administration of ivermectin (18 mg). Medical history was significant for hypothyroidism and cluster headache, with last attack reported some years before. She was not taking any medications other than levothyroxine (100 mcg daily). Ivermectin is usually described as a gamma-aminobutyric acid (GABA) neuronal pathway inhibitor with poor blood-brain barrier penetration, although high levels of the drug in the cerebrospinal fluid were detected in knockout mice for gene *mdr*-1 [26]. Chandler *et al*. reported serious neurological adverse events in 28 patients treated with ivermectin (dosage up to 24

mg, one or two doses) including ataxia, disturbed consciousness, seizures, encephalopathy or coma, starting within one day from the administration up to 7 days [26]. No patient was diagnosed with *Oncocherca volvulus*, and 10/28 (35.7%) of the population was specifically treated for scabies. Chandler *et al.* postulated that neurological ADRs were related to concomitant drugs or to polymorphism of *mdr*-1 gene. In our case, the patient presented symptoms after 2 weeks: considering the drug half-life of approximately one day (16-36 hours) and the positive medical history of cluster headache, symptoms were assumed to be unrelated to the drug [29]. Although pharmacological interactions between ivermectin and levothyroxine have not been reported, impaired GABA transmission was evidenced *in vitro* [30]. At 60 days from the treatment, patient general picture was slightly improving, and she was referred to a headache evaluation centre.

Considering drug costs reported by hospital pharmacy, our intervention with ivermectin cost a total of 423.69 euros, 3 times more than a hypothetical management with 5% permethrin cream (total of 137.75 euro). However, cost of drugs depends on the country: in fact, in several published observations, treatment with ivermectin was cheaper than permethrin cream [31]. Moreover, treatment with ivermectin is generally considered more comfortable and easier to use in mass drug administration and more reliable since the application is not individually dependent [9].

In our experience, single administration of ivermectin 200 mcg/kg was 100% effective for prevention of scabies in primary contacts of patient with clinically diagnosed classical scabies. Our observation has however several limitations. Firstly, the observation lacks a control population that did not received scabies prophylaxis; in addition, the number of at-risk contacts who took single-dose ivermectin is small. Moreover, patients with ADRs reported after 30 and 60 days from the treatment were evaluated only by phone or medical visit, without any supplementary examination, making the definition of ADRs uncertain. These limitations make the experience not sufficient to demonstrate the full efficacy of the prescribed dosage regimen.

CONCLUSIONS

To our knowledge, this is the first Italian experience in which use of a single dose of ivermectin was implemented for mass pre-emptive therapy in classic scabies primary contacts. This experience highlighted the excellent efficacy of the drug in preventing scabies even when used once in patients without symptoms. More data are needed to establish the correct approach (pre-emptive mass therapy and/or watch and wait for symptomatic cases) and ivermectin dosage (once, twice or more).

Authors' contributions

Conceptualization: AB, LZ, MC, GA, FN, AMP; Material preparation and data collection: RP, MP, BB; Data analysis: RP; First draft of the manuscript written by: RP, EM, GB, AI, AC, DP; Comments on previous versions of the manuscript: MP, BB, EM, GB, AB, LZ; All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Funding

The authors declare that they did not receive any support from any organisation for the submitted work.

Ethics approval and consent to participate

This retrospective study analysed the outcomes of ivermectin use in the prophylaxis and treatment of classical scabies in terms of ADRs and efficacy. Ivermectin is currently recommended in Italy for the treatment of scabies [16], and evaluation visits and follow-up calls are conducted according to the hospital internal procedures and literature [9].

Consent for publication

Oral consent to publish this experience was obtained during the 60-day follow-up call by all the hospital staff evaluated.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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